Policies and Review Process

It is the responsibility of the Chief Medical Officer (CMO) to serve as the IRB Chair at HJAHC. It is the responsibility of the IRB Chair or designee to:

- Review proposed human research protocols to determine if they require IRB review.
- Determine the type of review required of proposed human research projects.
- Provide information regarding the HJAHC IRB policies, processes, and requirements to Principal Investigators (PIs) of proposed human research projects.
- Maintain an active IRB committee and to ensure the composition of the IRB committee meets the requirements set forth in this policy
- Maintain a list of those individual members of the IRB committee who have sufficient experience and training to conduct facilitated and expedited reviews of proposed human research projects.
- Assign primary reviewers to conduct facilitated and/or expedited reviews of proposed human research projects, where appropriate.
- Convene full IRB meetings to discuss proposed human research projects.
- Notify PIs of decisions to approve, approve with conditions, or disapprove proposed human research projects.

PROCEDURE

1. Any new human subjects research projects to be conducted with HJAHC patients and/or staff will be submitted to and reviewed by the IRB Chair or designee.

2. The IRB Chair or designee will review the proposed human research project to determine if it is exempt from federal requlations. If exempt, the IRB Chair or designee will notify the project manager, in writing, of the decision.

    - New projects that may meet the federal criteria for exemption must be submitted to the HJAHC IRB for a determination.
    - The research may not start until the HJAHC IRB determines the project qualifies for exemption and supplies this determination in writing.

3. For all proposed human subjects research projects that require IRB approval, it is the responsibility of the IRB Chair or designee to:

    - Determine if the research project is appropriate for expedited review, facilitated review, or if the project requires a convened review process
    - Provide the PI with a copy of the HJAHC ‘IRB PROTOCOL REQUEST’ form. This form

will identify the PI and provide information regarding the study protocol, including but not limited to, the design of the study, possible participants, cost, potential risks, and a tentative timeline for completion
- Provide the PI with a copy of the HJAHC 'IRB Financial and Other Conflict of Interest' form;
- Provide the PI with a copy of the HJAHC Institutional Review Board policy.

4. Upon receipt of the completed 'IRB PROTOCOL REQUEST' form, completed 'IRB Financial and Other Conflict of Interest' form, and all required documents as indicated in the 'IRB PROTOCOL REQUEST' form, the IRB Chair or designee will initiate the IRB review process.

Process for Facilitated and Expedited Reviews:

- Facilitated and expedited reviews may be conducted by any member on the designated IRB reviewer list, with the exception of research involving a drug, biologic, or complementary alternative medicine, which must bereviewed by a pharmacist in addition to the IRB member, unless the IRB member conducting the review is also a pharmacist.
- Members will be added to the designated member list when the IRB Chair determines the member has sufficient experience and training to conduct such reviews.
- The IRB Chair or designee will assign a primary reviewer to conduct the review.
- The primary reviewer will conduct and complete the review within fourteen (14) business days of assignment. The review will be deemed complete upon notifying the IRB Chair of the decision to either approve the study, approve the study with conditions, or recommend the protocol to be reviewed during a convened meeting.
- A primary reviewer conducting a facilitated or expedited review is not authorized to disapprove an application; such action may only be taken at a convened meeting. Should the primary reviewer determine that the protocol should be disapproved, the primary reviewer will contact the IRB Chair in order to convene an IRB meeting.
- Process for Convened Review:
- Full committee IRB meetings will be scheduled on a quarterly basis.
- Under the guidance of the IRB Chair, the IRB Secretary will create an agenda for the scheduled meeting. The agenda will be provided to the IRB committee members prior to the start of the scheduled meeting.
- The IRB committee shall have at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by HJAHC.
- HJAHC shall maintain a list of IRB members. This list shall include the following

information: earned degrees; representation capacity; indications of experience (such as board certification); relationships of the members to HJAHC; office/role (such as Chair or Co-Chair).

- The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
- The IRB shall include at least one member whose primary concerns are in the scientific area and at least one member whose primary concerns are in nonscientific areas.
- The IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
- The IRB may not have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
- The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.
- The IRB may request that the PI and/or research affiliates attend all or part of the IRB meeting to make a formal presentation and to answer any questions.
- The IRB Chair will determine whether a quorum is present. The HJAHC IRB meeting will begin when quorum is present, including a non-scientific member.
- If it is determined in advance of a HJAHC IRB meeting that a quorum of members will not be available, the meeting will be canceled.
- If a quorum is present at the beginning of the meeting but is lost during the meeting, no further actions will be taken and the agenda items that had not been voted on will be transferred to the next available meeting, and the loss of quorum will be documented in the minutes.
- In the event that the Chair is called from the room or leaves early, the Chair may designate a IRB Secretary to continue the meeting. If both the Chair and Secretary are out of the room, the meeting may continue so long as quorum exists and the Chair or Secretary appoint a member to conduct the meeting.
- The IRB can elect to approve, approve with conditions, or disapprove a reviewed proposal.
- In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting
- The IRB Chair or designee will notify the PI of its decision in writing no more than fourteen (14) business days after the IRB committee convenes.

Process for Actions to Disapprove Research:

- When the IRB takes action to disapprove research, the PI will be provided with a written notification of the action. The notification shall explain the reasons for the decision.
- The PI may appeal the decision by submitting a response in writing or in person. In the event that an appeal is not submitted, or the IRB reviews the appeal and does not change its decision to disapprove the research, the decision of the IRB is final. Institutional officials may not approve research that has been disapproved by the IRB. No further appeal to override the IRB decision of disapproval may be made to HJAHC.

Process for Continuing Review of Research:

- The HJAHC IRB will conduct continuing review, which is substantive and meaningful, of approved ongoing research not less than once per year. The frequency of continuing review will be appropriate to the degree of risk. Continuing review will be based on receipt of appropriate progress reports from the investigator and include study-wide findings where available.

5. HJAHC requires IRB review and approval of additional study personnel.

- In the event that the PI would like to request the additional of new study personnel to their protocol, the PI must submit a completed HJAHC 'IRB Additional Study Personnel' form.
- The IRB Chair or designee will review and approve or disapprove the addition of new study personnel within fourteen (14) business days of receipt of the completed HJAHC 'IRB Additional Study Personnel' form.
- The additional study personnel may not participate in the approved study until the PI received written confirmation from the HJAHC IRB that the study personnel has been approved.

6. HJAHC requires IRB review and approval of proposed changes to approved research prior to initiation of any changes with one exception. The exception is a change in research necessary to eliminate apparent immediate hazards to a research participant. In cases where changes were made to eliminate apparent immediate hazards, it is the responsibility of the PI to inform the IRB promptly of the change and the IRB must determine if the modified research is consistent with ensuring participants' continued welfare. Changes in research may encompass amendments, addenda, deletions, or revisions to either the protocol or consent document associated with a protocol.

- In the event that the PI would like to request a change to an approved research protocol, the PI must submit a completed HJAHC 'IRB Modification Request' form.
- Upon receipt of the completed 'IRB Modification Request' form, the IRB Chair or designee will initiate the IRB review process as outlined above.

7. HJAHC requires continuing review of all approved research protocols.

    - The PI is responsible for submitting a completed HJAHC 'IRB Final Study Report Study Closure' form within 30 days of the expiration of their study.
    - Should the PI desire to extend their study past the initial expiration date, it is the responsibility of the PI to submit a completed HJAHC 'Continuing Review Application' form prior to the date of expiration of their protocol.
    - If the PI desires to extend their study past the initial expiration date, but fails to submit a completed HJAHC 'Continuing Review Application' form to the HJAHC IRB, the PI must submit a completed HJAHC 'IRB Expired Study Report' form in addition to the completed HJAHC 'Continuing Review Application' form.
    - Upon receipt of the completed HJAHC 'Continuing Review Application' form and 'IRB Expired Study Report' form, if applicable, the IRB Chair or designee will initiate the IRB review process as outlined above.
    - A PI's failure to submit a completed HJAHC 'IRB Final Study Report_Study Closure' form within 30 days of the expiration of their study or to submit a completed HJAHC 'Continuing Review Application' prior to the date of expiration of their protocol is itself an incident of non-compliance. Incidents of non-compliance will be managed in accordance with the HJAHC IRB Policy on Investigator Non-Compliance.

8. HJAHC requires the IRB to review any unanticipated problem or adverse event associated with an approved protocol.

    - It is the responsibility of the PI to report the occurrence of any incident, experience, outcome or adverse event that meets all three (3)of the following criteria:
    - The incident, experience, outcome or adverse event is unexpected in terms of nature, severity or frequency, given the research protocol, IRB-approved informed consent document, and given the characteristics of the subject population being studied; and
    - The incident, experience, outcome or adverse event is related or possibly related to participation in the research;
    - The incident, experience, outcome or adverse event potentially places the research subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or

recognized.

- Should the PI determine that the incident, experience, outcome or adverse event meets all three (3) criteria as outlined above, the PI must submit a completed HJAHC 'IRB Unanticipated Problem Adverse Event' form.
- Serious adverse events that involve the death of a subject or are considered to be life-threatening need to be reported to the HJAHC IRB within 1 business dat of discover (telephone, fax, email) with a full report submitted via completion of the HJAHC 'IRB Unanticipated Problem Adverse Event' form within 48 houts of the initial notification.
- All other unanticipated problems must be reported within 7 business days of discovery via completion of the HJAHC 'IRB Unanticipated Problem Adverse Event' form.
- The IRB Chair or designee will review the HJAHC 'IRB Unanticipated Problem Adverse Event' form within fourteen (14) business days of its receipt.
- The IRB Chair or designee will provide the PI a determination regarding how any unanticipated problem or adverse event should be handled (e.g. study termination, protocol modification, notification of current or former study participants, Corrective Action Plan, etc.).
- A PI's failure to submit a completed HJAHC 'IRB Unanticipated Problem Adverse Event' form within the timeline as noted is itself an incident of non-compliance. Incidents of non-compliance will be managed in accordance with the HJAHC IRB Policy on Investigator Non-Compliance.

9. HJAHC requires the IRB to review any protocol deviation. A protocol deviation is a departure from the approved protocol's procedures made with or without prior IRB approval. It is the responsibility of the PI to contact the HJAHC IRB in the event that a protocol deviation occurs. There are three types of deviations from protocol procedures recognized by the HJAHC IRB, and each type has a different IRB reporting requirement:

Emergency Deviations:

- Emergency deviations are those occurring in an emergency situation, such as when a departure from the protocol is required immediately to protect the life or physical well-being of a participant. In such cases there is no time to prospectively seek the approval of the IRB.
- The sponsor and the IRB of record must be notified as soon as possible, but not later than 5 days after the emergency situation occurred.
- The PI must submit a report to the IRB of record by submitted a completed HJAHC 'IRB Protocol Deviation' form. Deviations of this nature are always considered to be unanticipated problems involving risks to subjects or others.

Major, Non-Emergent Deviations:

- Major, non-emergent deviations are planned deviations that are non-emergent and represent a major change in the approved protocol. Examples include exceptions to eligibility criteria, exceptions to the form and manner of obtaining informed consent, and exceptions to the schedule of administration of an investigational product. Modifications to existing protocols must be submitted and reviewed as noted above.
- If a planned major, non-emergent deviation occurs without prior IRB approval, the event is non-compliance which must be reported promptly to the IRB by submitting a completed HJAHC 'IRB Protocol Deviation' form. A PI's failure to report promptly any major, non-emergent deviation for which the PI did not obtain prior approval is itself an incident of non- compliance. Incidents of non-compliance will be managed in accordance with the HJAHC IRB Policy on Investigator Non- Compliance.

Minor or Administrative Deviations:

- Minor or administrative deviations are those which do not "affect the scientific soundness of the research plan or the rights, safety, or welfare of human subjects." Examples of minor or administrative deviations include: follow up visits occurring outside the protocol required time frame because of the participant's schedule, or blood samples being obtained at times close to but not precisely at the time points specified in the protocol.
- If a protocol deviation occurs which meets this definition, the deviation should be reported to the HJAHC IRB at the time the continuing review application is submitted by submitting a completed HJAHC 'IRB Protocol Deviation' form.