If you have a conflict of interest that would require you to be recused for the review of this protocol, please contact the IRB Office to arrange for reassigning this protocol. specify if the research meets Criteria for Approval outlined below by checking the corresponding box. Please document your concerns in the corresponding comments box. Complete and submit this form to [IRBOffice@khcc.jo](mailto:IRBOffice@khcc.jo).

| Research Title: | | |
| --- | --- | --- |
| Project No.: | | |
| Initial Review | Continuing Review | Amendment |

| **Criteria for IRB review and approval** | **Review Guidelines** | **Comments** |
| --- | --- | --- |
| **Scientific merit** | Background information and relevant data justify doing the research  The research design, methods and procedures are consistent with scientifically sound research  The research design is able to answer its proposed question;  The knowledge expected to result from this research is sufficiently important.  Only data pertinent to answering the research question will be collected  Investigator(s) and research team appropriately qualified by education and training to conduct the study  Adequate time for the investigator to conduct and complete the research. |  |
| **Risk and potential benefit** | Clear differentiation between standard procedures and research procedures  Procedures are consistent with sound research design  Procedures do not unnecessarily expose participants to risk.  Risks to participants are minimized (i.e. precautions to decrease the likelihood or magnitude of harm)  Risks to subjects are reasonable in relation to anticipated benefits and the importance of the knowledge that may be expected to result  Adequate provision for monitoring the data collected to ensure the safety of participants  Adequate provisions to continue, modify or immediately stop the study, when the risks are found to outweigh the potential benefits or when there is conclusive proof of definitive outcomes  Adequate provisions, medical or psychosocial, to deal with harms if they occur  Unanticipated Problem reporting is adequately addressed |  |
| **Recruitment of participants** | Appropriate subject population  The selection of participants is equitable.  Appropriate inclusion/exclusion criteria  The setting, timing and location of recruitment are appropriate  Recruitment procedures are appropriate  Recruitment material do not constitute coercion or undue influence  Screening procedures are appropriate |  |
| **Privacy and confidentiality** | Adequate provisions to protect the privacy of participants  Appropriate provisions to maintain the confidentiality of data. |  |
| Vulnerable populations | Does the research include vulnerable populations?  No  Yes:  Additional safeguards have been included in the study to protect these groups from harm and secure their rights.  The research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group.  This group stands to benefit from the knowledge, practices or interventions that result from the research. |  |
| Recruitment incentives, financial benefits, and financial costs | Payment in exchange for referrals of prospective participants from others (“finder’s fees”) is not permitted. Similarly, payments designed to accelerate recruitment that is tied to the rate or timing of enrollment (“bonus payments”) are not permitted.  proposed payments are reasonable and commensurate with the expected contributions of the participant  Proposed payments do not constitute (or appear to constitute) undue pressure on the participant to volunteer for the research  Payment is not contingent upon completion of the study |  |
| Compensation for injury | Appropriate compensation and treatment coverage for participants who are harmed as a result of participating in research. |  |

| **Informed Consent** | |
| --- | --- |
| Informed consent will be sought from each prospective subject or the subject’s legally authorized representative, in accordance with, and to the extent required by the regulations.  Waiver of consent or elements of consent is requested  Waiver of Documentation of consent is requested | |
| If waiver is Requested, I recommend ( NA):  granting the waiver based on the justification provided, please explain:  Not granting the waiver based on the justification provided, please explain: | |
| If informed consent will be obtained ( NA, waived):  The informed consent process is appropriate  The language of consent is appropriate  Informed consent will be appropriately documented | Comments: |
| **Does the informed consent document include all required elements of consent? ( NA, waived)** | |
| A statement that the study involves research |  |
| An explanation of the purposes of the research |  |
| The expected duration of the subject's participation |  |
| A description of the procedures to be followed |  |
| Identification of any procedures which are experimental |  |
| A description of any reasonably foreseeable risks or discomforts to the subject |  |
| A description of any benefits to the subject or to others which may reasonably be expected from the research. |  |
| A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject |  |
| A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the regulatory authorities may inspect the records. |  |
| An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject. |  |
| A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled |  |
| Information concerning the compensation, including the amount and schedule of payments, is included in the consent document. |  |
| The consent form should describe the terms of payment and the conditions under which participants would receive partial payment or no payment. |  |
| The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject |  |
| A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject. |  |
| The approximate number of subjects involved in the study. |  |
| For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of and who will pay for the treatment and whether other financial compensation is available, or where further information may be obtained. |  |
| A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable. |  |
| Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent. |  |

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| Based on the information in the protocol, I recommend that the study be:  **Approved**  **Approved with explicit conditions**, provide explanation:  **Deferred until more information is obtained**, provide explanation:  **Disapproved**, provide explanation:  The research should be subject for continuing review every  12 M  6 M  other: |