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. Please review and specify if the research meets Criteria for Approval outlined below by checking the corresponding box. Document your comments in the corresponding box. Submit the completed form to [IRBOffice@khcc.jo](mailto:IRBOffice@khcc.jo).

The following cannot be reviewed by the expedited procedure:

* The research where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
* A research that involves interaction or intervention with a vulnerable group such as children cannot be reviewed by the expedited procedure and should be referred to full-board review. This does not apply to research involving secondary analysis of existing data.

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| --- | --- | --- | --- | --- | --- | --- | --- |
| Research Title: | | | | | | | |
| Project No.: | | | | | | | |
| Initial Review | | Continuing Review | | | Amendment | | |
| **Criteria for IRB Review and Approval** | | | | | | | |
| (a) 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. | | | | | | Comments: | |
| **(b) 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 | | | | | | Comments: | |
| (C) 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 | | | | | | Comments: | |
| (d) Privacy and Confidentiality  Adequate provisions to protect the privacy of participants  Appropriate provisions to maintain the confidentiality of data. | | | | | | Comments: | |
| (e) Vulnerable Populations  Does the research include vulnerable populations?  No  Yes, if 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. | | | | | | Comments: | |
| (f) 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 | | | | | | Comments: | |
| (g) Compensation for Injury  Appropriate compensation and treatment coverage for participants who are harmed as a result of participating in research. | | | | | | Comments: | |
| **Informed Consent** | | | | | | | |
| Will informed consent be sought?  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:  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. | | | | | |  | |
| **Protocol Risk Assessment**  *Minimal Risk: A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*  Based on the aforementioned definition this protocol qualifies as:  no more than minimal risk  Greater than minimal risk  Please, provide a rationale for your assessment (If reviewing for continuing review or an amendment, include rationale for the change in the risk assessment from initial review): | | | | | | | |
| **The following Expedited Categories apply to the protocol:** | | | | | | | |
| **Category 1:** Clinical studies on marketed drugs and medical devices when the following conditions are met (Note: Research on marketed drugs/ medical devices that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.):   1. it is not intended to be reported to regulatory authorities whether in Jordan or in other countries in support of a new indication for use or to support any other significant change in the labeling for the drug 2. it is not intended to support a significant change in the advertising for the product 3. it does not involve a route of administration or dosage level, use in a subject population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the product 4. it is conducted in compliance with the requirements concerning the promotion and sale of drugs/devices   **Category 2:** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:  (a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or  (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.  **Category 3:** Prospective collection of biological specimens for research purposes by noninvasive means.  Examples:  (a) hair and nail clippings in a non-disfiguring manner;  (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;  (c) permanent teeth if routine patient care indicates a need for extraction;  (d) excreta and external secretions (including sweat);  (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;  (f) placenta removed at delivery;  (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;  (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;  (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;  (j) sputum collected after saline mist nebulization.  **Category 4:** Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)  Examples:  (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects privacy;  (b) weighing or testing sensory acuity;  (c) magnetic resonance imaging;  (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;  (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.  **Category 5:** Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt (**Category 3**). This listing refers only to research that is not exempt.)  **Category 6:** Collection of data from voice, video, digital, or image recordings made for research purposes.  **Category 7:** Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt (**Category 2)**. This listing refers only to research that is not exempt.)  **Expedited Categories for Continuing Reviews only**  **Category 8:** Continuing review of research previously approved by the convened IRB as follows:  (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or  (b) where no subjects have been enrolled and no additional risks have been identified; or  (c) where the remaining research activities are limited to data analysis.  *Note: For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever the conditions of category (8)(a), (b), or (c) are satisfied for that site. However, with respect to category 8(b), while the criterion that "no participants have been enrolled" is interpreted to mean that no participants have ever been enrolled at a particular site, the criterion that "no additional risks have been identified" is interpreted to mean that neither the investigator nor the IRB at a particular site has identified any additional risks from any site or other relevant source.*  **Category 9:** Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.  None of the described categories apply | | | | | | | |
| Based on the information in the protocol, I have made the following determination:  The research is approved under the expedited procedure as it meets the categories described earlier.  Modifications or further explanations described below are required before a decision can be made:    The activity is not eligible for expedited review and must be reviewed by the full IRB, provide a brief explanation:  Does the research require review more frequent than annually?  No  Yes, specify recommended review frequency: | | | | | | | |
|  |  | |  |  | | |  |
|  | **Reviewer’s Name &Signature** | |  | **Date** | | |  |