###  Notice of Substantial Amendment

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| *Please use this form if you are requesting a substantial amendment to a REC approved and ongoing protocol. Please fully describe and justify your proposed amendment and submit all relevant documents for REC review.* ***Amendments to protocols may not be initiated until REC approval has been obtained.*** |
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| 1. GENERAL PROTOCOL/STUDY INFORMATION  |
| Name of Research Permit Operator: Research Permit #/Issue Date: Protocol / Study Title:Protocol / Study No. (if applicable): Lead Site Location:RERC reference No. Date study commenced: Expected End Date:Name of Principal Investigator (PI) or DHCC Lead PI: Department *(if applicable)*: Title: |
| 2. STATUS OF PROTOCOL (please indicate below) |
| Open to Enrollment: [ ]  Currently enrolling subjects [ ]  No enrollment to date Closed to Enrollment, however:[ ]  Study treatment/intervention/procedures continues [ ]  Active or long term follow-up continues  [ ]  Data analysis is ongoing |
| 3. RISK-BENEFIT ASSESSMENT (please check all that apply) NOTE: Please explain how the risk-benefit ratio of subjects is affected in the Description of Changes. |
| Please indicate if the amendments you wish to propose affect the risk-benefit ratio for subjects:[ ]  No change to risk [ ]  May increase risk [ ]  May decrease risk |
| 4. TYPE OF AMENDMENT  |
| 1. **Amendment to information previously given in RERC application**
 |
| [ ]  Yes [ ]  No *If yes, please provide a description of the changes*  |
| **B. Amendment to the Protocol Components**  |
| Amendments initiated by[ ]  Investigator [ ]  Sponsor [ ]  Other (*please specify*): |
| *Please indicate below the protocol components to be modified:* |
|  [ ]  Protocol Title |  [ ]  Study Design |  [ ]  Study Type |  [ ]  Sponsor |
| [ ]  Funding  Source/Budget |  [ ]  Study Sites |  [ ]  Site Enrollment  (Number of Subjects) |  [ ]  Subject Eligibility  and/or Exclusion  Criteria |
|  [ ]  Recruitment  Procedures and/or  Materials  |  [ ]  Consent Procedures  and Materials |  [ ]  Duration of Subject  Participation |  [ ]  Types of Subjects |
|  [ ]  Special Population(s) |  [ ]  Subject Age Range |  [ ]  Remuneration |  [ ]  Patient Diaries |
| [ ]  Research Related  Use of Medical  Records | [ ]  Research Related Use  of Discarded Material | [ ]  Use of Specimens | [ ]  Data Collection  Methods or  Instruments |
| [ ]  Intervention or  treatment procedure | [ ]  Drug—Usage and Type | [ ]  Device—Usage and  Type | [ ]  Biologic—Usage and  Type |
|  [ ]  Other *(please specify*):*Please submit either the revised protocol with a new version number and date, highlighting changed in bold or submit a document listing the changes and giving both the previous and revised text*  |
| Amendment to the information sheet (s) and consent forms (s) for subjects, or to any supporting documentation and/or procedures |
|  [ ]  Yes [ ]  No |
| *If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold and provide a description of the changes* **1)** Will this amendment require Re**-**Consent of previously enrolled subjects? [ ]  Yes [ ]  No If yes, please *describe the re-consenting process and provide justification*  |
| **2)** Recruitment Materials? [ ]  No [ ]  Yes🡪*If* ***yes****, submit a copy of revised recruitment materials*  |
| **3)** Study Materials? [ ]  No [ ]  Yes🡪 *If* ***yes****, please submit a copy of revised study materials  (e.g. surveys, questionnaires, study handouts, etc.)* |
| **4)** Cohort or Subject Population? [ ]  No [ ]  Yes🡪 *If* ***yes****, please provide explanation*  |
| **5)** Investigator Conflict of Interest? [ ]  No [ ]  Yes🡪*If* ***yes****, please submit a new Investigator Disclosure  or Investigator Certification form(s), as applicable*  |
| **6)** Other *(please specify*): |
| Is this a modified version of a previously notified and not approved amendment? |
| [ ]  Yes [ ]  No |
| **Summary of changes**Briefly describe the main changes proposed in this amendment, explaining the purpose and significance for the study. If this is a modified amendment  |
| E. Study Site Personnel (Please indicate below all study personnel to be added and removed from this protocol) NOTE: Include CVs of all new individuals in addition to copies of GCP training certification. All study personnel require RERC approval prior to conducting any study procedure(s). |
| *Study Personnel* | *Subject Interaction*  | *Obtains**Informed Consent* | *Conducts data analysis, reviews medical records/ databases and/or handles biological specimens* |
| Name:Title:Entity/Department:Role in study:[ ]  Add to Protocol [ ]  Remove from ProtocolEmail:GCP Training? [ ]  Yes [ ]  NoIf yes, specify type: | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
| *Study Personnel* | *Subject Interaction*  | *Obtains**Informed Consent* | *Conducts data analysis, reviews medical records/ databases and/or handles biological specimens* |
| Name:Title:Entity/Department:Role in study:[ ]  Add to Protocol [ ]  Remove from ProtocolEmail:GCP Training? [ ]  Yes [ ]  NoIf yes, specify type: | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
| Name:Title:Entity/Department:Role in study:[ ]  Add to Protocol [ ]  Remove from ProtocolEmail:GCP Training? [ ]  Yes [ ]  NoIf yes, specify type: | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
| Name:Title:Entity/Department:Role in study:[ ]  Add to Protocol [ ]  Remove from ProtocolEmail:GCP Training? [ ]  Yes [ ]  NoIf yes, specify type: | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |

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| 5. Description of Changes (*Please fully describe each amendment stated in Section 4 and its effect on protocol integrity and the risk-benefit ratio. Provide a complete rationale and justification for each modification e.g., Subject Eligibility: eligibility age range is 30 to 50 yrs).* |
|  : Amendment Category |
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| 6. INVESTIGATOR ASSURANCE |
| As Principal Investigator, by signing this application:* I accept ultimate responsibility for the protection of the rights and welfare of the human subjects, the conduct of this study, and the ethical performance of this project
* I have read and agree to comply with the DHCR Research Regulations
* I agree to comply with all applicable DHCR policies and procedures, as well as with all relevant local and international laws regarding the protection of human subjects in research
* I will personally conduct or supervise this research within DHCC and accept responsibility for adhering to the RERC-approved protocol
* I understand that no modifications may be made to the protocol, study documents and/or informed consent document prior to DHCR RERC approval
* I understand that approval of this research could be suspended or terminated by RERC and/or Academic and Research Council
* I understand that any research-related material is subject to an audit by the DHCR Academic and Research department
* I certify that the proposed research is not currently being conducted and will not begin until RERC approval has been obtained
* I have completed the human subject protection education requirement and ensure that all investigators and personnel involved in this research have competed the human subject education requirements
* I certify that the information provided in this application is complete and accurate
* I certify that the proposed amendments will not be implemented until RERC approval has been obtained

  Signature of Principle Investigator Date |
| 7. ADDITIONAL SIGNATURES |
| **Signature of Associated PI** | **Signature of Research Permit Holder** | **Date** |
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| **do not complete this section. for official rec use only.** |
| Review Procedure: [ ]  Full [ ]  Expedited | Date of Full Board Review:  |
| Name of Primary Reviewer: | Date of Review: |
| Name of Secondary Reviewer: | Date of Review: |
| Decision Status: [ ]  Approve [ ]  Approve with Modification [ ]  Defer [ ]  Deny  |
| Signature of REC Chair:  | Date returned to A&R: |