### 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 Protocol  Email:  GCP Training?  Yes  No  If 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 Protocol  Email:  GCP Training?  Yes  No  If yes, specify type: | | | Yes  No | | Yes  No | | Yes  No | | | |
| Name:  Title:  Entity/Department:  Role in study:  Add to Protocol  Remove from Protocol  Email:  GCP Training?  Yes  No  If yes, specify type: | | | Yes  No | | Yes  No | | Yes  No | | | |
| Name:  Title:  Entity/Department:  Role in study:  Add to Protocol  Remove from Protocol  Email:  GCP Training?  Yes  No  If 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: |