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| --- | --- |
| **Biomedical Amendment** | **For Internal Use Only** |
| **UnivRS Internal ID:**  **Date Received:** Click here to enter a date. |

**Questions marked with an** \* **are mandatory.**

**Key Information**

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| --- |
| UnivRS Internal Project ID# or old Ethics ID # (Bio xx-xxx):\*  PI Name: \*  Protocol # (if applicable):  Project originally approved by: \*  Delegated Review  Full Board Review  Title: \* |

**Change to Study Title**

|  |
| --- |
| Are you changing the study title? Yes  No  New proposed title: |

**Project Status**

|  |  |  |
| --- | --- | --- |
| Summarize and provide reasons for proposed revision(s): \*   |  | | --- | | Indicate the current status of this project: \* Choose an item.  If ‘Other’ was selected, specify: | | How will participants be notified of proposed changes: Choose an item.  If ‘Other’ was selected, specify:  If ‘re-consented’ was selected, specify the number of participants affected:  If ‘re-consented’ was selected, outline the procedure: | |

**Health Canada**

|  |  |  |
| --- | --- | --- |
| |  |  | | --- | --- | | Does this Amendment require a submission to Health Canada? \*  Yes  No; If not required, explain:  If yes, provide the REB with a copy of the applicable Health Canada authorization along with this amendment. |  | |

**Change to Sponsor(s) and Agency(ies)**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Sponsor(s)** *A sponsor takes responsibility for the initiation and management of research and compliance with applicable regulations. The sponsor may or may not be the main funding organisation****.***   |  |  | | --- | --- | | **Add / Remove:** | **Sponsor:** | |  |  |   **Agency(ies)** *An agency(ies) provides funding to support research projects.*   |  |  | | --- | --- | | **Add / Remove:** | **Agency:** | |  |  |   Project Application(s) Directly Associated with the Fund(s) Supporting this Project.  Specify the UnivRS internal ID# (for pending grants or contracts):  Project(s) Directly Associated with the Fund(s) Supporting this Project.  Specify the UnivRS internal ID# (for awarded grants or contracts): |

**Change to Location(s) Where Research Activities Are Conducted**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | | **Add Remove:** | **Building or Organization:** | **Country:** | |  |  |  | |

**Change to Project Team and Contacts**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Principal Investigator**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **New PI Name:** | **NSID:** | **Email:** | **Phone:** | **Organization (Department):** | |  |  |  |  |  |   **Sub-Investigator(s)**   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Add Remove:** | **Name:** | **NSID:** | **Email:** | **Phone:** | **Organization (Department):** | |  |  |  |  |  |  |   **Student(s)**   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Add Remove:** | **Name:** | **NSID:** | **Email:** | **Phone:** | **Organization (Department):** | |  |  |  |  |  |  |   **Primary Contact**   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Add Remove:** | **Name:** | **NSID:** | **Email:** | **Phone:** | **Organization (Department):** | |  |  |  |  |  |  |   **Secondary Contact**   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Add Remove:** | **Name:** | **NSID:** | **Email:** | **Phone:** | **Organization (Department):** | |  |  |  |  |  |  | |

**Declaration by Principal Investigator:**

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| |  |  | | --- | --- | | **By submitting this amendment form, the Principal Investigator confirms that they are responsible for the scientific and ethical conduct of this project and agrees to conduct this project in compliance with the current version of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, the Health Information Protection Act (HIPA) and any other relevant laws, regulations or guidelines.**  Date the form was completed: Click here to enter a date. | | | Name of Person who completed the form |  |   If form submitted on behalf of the PI:   |  |  | | --- | --- | | is authorized to prepare and submit this form on behalf of the Principal Investigator | | | Authorized person contact information: | | | Email: | Phone: | |

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| **Attached Document(s):** |

**Provide a list of Documents that are being submitted.**  **Revised documents should be submitted with changes tracked or highlighted, indicating the version number or date:**

|  |  |  |
| --- | --- | --- |
| **Document** | **Version** | **Date** |
| Protocol |  |  |
| Protocol Summary of Changes |  |  |
| Main Consent Form: Track Change Version |  |  |
| Other Consent Form(s) |  |  |
| Health Canada No Objection Letter |  |  |
| Sponsor Letters (s) |  |  |
| Participant Materials (please list) |  |  |
| Other Documents: |  |  |
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