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| **Biomedical Renewal**  **Prospective** |
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**Questions marked with an** \* **are mandatory.**

**Responses apply to the current reporting period for the local site.**

**Key Information**

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| Ethics ID # (Bio #):\*  PI Name: \*  Protocol Number (if applicable):  Current Protocol Version Date:  Project Title: \*  Current Expiry Date :\*  Project originally approved by: \*  Delegated Review  Full Board Review  Indicate the current status of this project in the drop down menu: \* Choose an item.  If “Other” was selected, provide additional details as applicable:  Provide a brief summary of the project progress at the local site: \* |

**Determination of Level of Review**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| **Complete Section A or B**   |  |  | | --- | --- | | **Section A:** | | | **This section applies to all research NOT regulated by the US Food and Drug Administration (FDA) or funded by the US Federal Government:** | | | Are the protocol and the risk level of the research unchanged? | Yes  No | | **Section B:** | | | **This section applies to all research regulated by the US Food and Drug Administration (FDA) or funded by the US Federal Government. Select ONLY one of the options below:** | | | The research is (i) permanently closed to the enrollment of new participants; (ii) all participants have completed all research related interventions; and (iii) the research remains active only for long-term follow up of participants; **OR** | Yes  No | | No participants have been enrolled (ever) and no additional risks have been identified; **OR** | Yes  No | | The remaining research activities are limited to data analysis. | Yes  No | |  | | | **If yes was answered in any of the 4 options (in section A or B) above, continuing review will be conducted by delegated review. Otherwise, full board review is required.** | | | **FULL BOARD REVIEW REQUIRED:** | Yes  No | |

**Participants**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  | | --- | --- | | Target/expected number of participants (according to the protocol): \* |  | | Number of participants who consented: \*  **[?]** |  | | Number of participants who were excluded based on the inclusion or exclusion criteria after consenting (screen fails): \*  Number of participants who are currently receiving treatment/study intervention: \* |  | | Number of participants who have completed treatment/study intervention and are in follow-up: \* |  | | Number of participants who have completed all study procedures (follow-up completed): \* |  | | Number of participants who were lost to follow-up: \* |  | | Number of participants who withdrew consent (stopped participating in the project): \* |  | | Number of participants who were withdrawn (by the study doctor, sponsor etc.) during the project: \* |  | | Number of participant non-research related deaths (i.e. unrelated adverse event), while participating in the project: \*  Number of participant research related deaths, while participating in the project: \* |  |   Provide additional details as applicable: |

**Post-Approval Reporting**

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| |  |  | | --- | --- | | |  | | --- | | **Reportable Unanticipated Problems include any incident, experience or outcome (including an adverse event or breach of confidentiality) that meets ALL of the following criteria:**   1. Unexpected in terms of nature, severity or frequency; 2. Related or possibly related to participation in research; 3. Suggests that research places research participants or others at a greater risk of harm than was previously known or recognized. | |  |  |  | | --- | --- | | Were there unreported, unanticipated problems that fit the reporting criteria? \* | Yes  No | | Were there unreported participants' concerns or complaints? \* | Yes  No |  |  |  | | --- | --- | | Has there been a change to data storage or data security arrangements? \* | Yes  No | | Have there been any changes in relation to the conflict of interest status of the PI and/or other members of the study team? \* | Yes  No | | Is there any new information that may adversely affect the safety or wellbeing of research participants? \* | Yes  No | | If you answered ‘Yes’ to any of the above questions, please explain. | | | Does this project have a Data Safety Monitoring Board (DSMB)? \* | Yes  No |   If yes, what is the reporting schedule of the DSMB?  What was the date of the last DSMB report submitted to the REB? Click here to enter a date.  What was the outcome of the report?  Outline any aspect(s) of this project which should be brought to the attention of the REB (i.e. breaches of confidentiality, major protocol violations, etc.) or specify Not Applicable (N/A) \* |

**Changes to Research Personnel**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| Changes to the PI, students, and/or Funder/Sponsor must be submitted using the amendment form.  **Sub-Investigator(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 renewal 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 all 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: | |

**Document(s)**

Please provide a list of documents that are being submitted along with this renewal, as applicable: