## PARKWAY INDEPENDENT ETHICS COMMITTEE

## STUDY AMENDMENT COVER NOTE

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| Changes to research may not be initiated prior to PIEC approval except as necessary to eliminate apparent immediate hazard to subjects here for amendments must be approved by the PIEC and Health Sciences Authority (for HSA-regulated research) prior to implementation. |

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| **PIEC Reference Number:** | Text Field |
| **Protocol Title:** | Text Field |
| **1 (a) Are there any change in the study / amendments to the previously approved study documents?**  Yes  No  *If ‘Yes”, please submit a copy of the revised document in ‘tracked changes’ format as well as a “clean” copy of the revised document.*  **(b) Please select the document(s) revised or change required (check multiple options if applicable):**  Protocol  Informed Consent Document  Recruitment Materials  Change in Recruitment Target  Change in Study Team Members (please include Annex B –Conflict of Interest Declaration Form)  Other, please specify: Text Field (c) Should the enrolled study subjects be informed/re-consented of these changes? Yes  No | |
| **2 (a) Are there any addition of new study document(s)?**  Yes  No  *If ‘Yes”, please submit a copy of the new document.*    **(b) Please list down the document(s) added.**  Text Field | |
| **3 (a) Has study enrolled any subjects?**  Yes  No  **(b) Please indicate the number of subjects affected by the proposed amendment(s).**  Text Field  **(c) How will subjects be affected by the proposed amendment(s)?**  Text Field | |
| **4. Amendment Details:-**  Amendment Category: Text Field  Purpose of Amendment  Text Field  Summary of Change  Text Field   |  | | --- | | **IMPORTANT: Please use the following format for each amendment:-**   * Amendment Category\* * Purpose of Amendment * Summary of Change (*can be submitted in a separate attachment if available*) * Location of Amendment (Page number, Section heading) * Original Text * Revised Text * Rationale for change | | ***\*Amendment Category***  **Category A: Substantive Revision:** *Revisions that negatively affect the risk benefit ratio or significantly affect the nature* *of the study.*  **Category B: Minor Revision:** *Revisions that pose no increase in risk more than minimal risk or new procedures added that fit within the categories eligible for expedited review.*  **Category C: Administrative Change:** *Change in addresses, contacts, etc. and correction of typographical /grammatical errors.* | | |

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| **Declaration of Principal Investigator:** |
| **I confirm that the information submitted in the above study status report is true and accurate at the date of submission of the report.**   |  |  |  | | --- | --- | --- | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | *Principal Investigator’s Signature* | | *Date* | |  |  | | | *Full Name:* | Text Field | | | *Institution:* | Text Field | | | *Department:* | Text Field | | |