* All amendment submissions should be forwarded to the General Manager of the Healthscope hospital.
* Please attach a copy of the HREC approval letter, as well as any document that require governance review.

|  |  |  |
| --- | --- | --- |
| **1. Project Details** | | |
| **Healthscope Hospital Details:** | |  |
| **Study Title:** | |  |
| **Study Acronym:** | |  |
| **Study Sponsor:** | |  |
| **Principal Investigator:** | **Name:** |  |
| **Study Coordinator (administrative contact):** | **Name:** |  |

|  |
| --- |
| **2. Reason for Amendment** |
| **Please summarise the changes and provide a brief reason for this amendment:** |
|  |

|  |  |  |  |
| --- | --- | --- | --- |
| **3. Study Documents for submission** | | | |
| **Please indicate the type of study documents being submitted.**  *NB: If there are changes to site specific document(s), tracked and clean copies of these documents must be submitted.* | | | |
| **Submission document** | | **Document Title** | **Version and Date** |
|  | Protocol |  |  |
|  | Investigator Brochure |  |  |
|  | Participant Information and Consent Form (PICF) |  |  |
|  | Quality of Life Forms |  |  |
|  | Contracts / Indemnity |  |  |
|  | Study document  (specify): |  |  |
|  | Other participant material  (specify): |  |  |
|  | Insurance Certificate  (specify): |  |  |
|  | Safety Notification  (specify): |  |  |
|  | Site Closure  (specify): |  |  |
|  | Other  (specify): |  |  |

|  |
| --- |
| **4. Signature of Principal Investigator** |
| I certify that the information in this form is truthful, accurate and complete to the best of my knowledge.  I understand that this amendment must not be implemented at the Healthscope hospital until acknowledgment has been granted by the hospital.  The project is being conducted in keeping with the conditions of approval of the reviewing HREC and in accordance with the protocol. The project is being conducted in compliance with the National Statement on Ethical Conduct in Human Research (NHMRC, 2007) and Safety monitoring and reporting in clinical trials involving therapeutic goods (NHMRC, 2016), or as amended.  **Name of the Principal Investigator / delegate\*:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_    **Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *(NB: A delegate may sign this form in place of the PI , as long as the PI is copied in to the submission email)* |