This form must be submitted to the Bolton Clarke HREC (ethics@boltonclarke.com.au) in the event that an ethically approved research project requires amendment. Any amendments must not be implemented until an updated copy of the approval letter is received.

## Research Project Details

**Bolton Clarke HREC Approval Number**: Click or tap here to enter text.

**Title of Research Project:** Click or tap here to enter text.

**Project Number:** Click or tap here to enter text.

**Primary Investigator:** Click or tap here to enter text.

## Amendment Details

**Explain the changes that you intend to make (*may include changes in procedure, direction of project, source/manner of recruitment, number of participants or changes to research personnel)***

Click or tap here to enter text.

**Explain the reason for the changes (*include a comment on the impact on the research project and participants)***

Click or tap here to enter text.

**Do these changes raise any ethical issues not covered in the initial approved project?**

Choose an item.

**If Yes, identify the ethical issues**

Click or tap here to enter text.

## Documents

**Please list all amended documents to be reviewed. Please provide a clean and tracked change versions of each of the listed documents**

|  |
| --- |
| Document Title (*include version number, if applicable*) |
| Click or tap here to enter text. |
| Click or tap here to enter text. |
| Click or tap here to enter text. |
| Click or tap here to enter text. |
| Click or tap here to enter text. |

Primary Investigator Declaration

I confirm that this project is being conducted in keeping with the conditions of approval of the reviewing HREC (and subject to any changes subsequently approved).

I confirm that the project is being conducted in compliance with the NHMRC National Statement on Ethical Conduct in Human Research (NHMRC, 2018)

I confirm that we will not implement any proposed amendments until an updated copy of the approval letter is received.

I am aware the HREC may determine that additional review, or a new study submission is required, if the amendment is significantly substantial.



Signature (insert above)

Name: Click or tap here to enter text.

Date: Click or tap here to enter text.