For an amendment to an ethically approved research project, submit the completed form to the *reviewing*
Human Research Ethics Committee (HREC)

**An amendment must not be implemented at a site until HREC approval has been given and, if applicable,
Site Specific Assessment (SSA) amendment has been authorised**

## Research Project

|  |  |  |  |
| --- | --- | --- | --- |
| HREC reference Number | E.g. HREC/12345/MH-2019 | HREC approval date |       |
|  |
| **Local Reference Number** | E.g. 2019.123 | **Date of this form** |       |
|  |
| **Project title** | Enter text |
|  |  |
| **Sponsor** | Enter text | **Sponsor telephone** | Enter text |
|  |
| **Sponsor contact (Aus)** | Enter text | **Sponsor email** | Enter text |
|  |  |  |  |
| **Sponsor billing address** | Enter text |
|  |
| **Coordinating Principal Investigator (CPI) for project** | Enter text |
|  |
| **CPI email** | Enter text |  |  |
|  |
| **Study coordinator name** | Enter text | **Study coordinator email** | Enter text |

## Amendment

|  |  |
| --- | --- |
| Did a commercial sponsor initiate the amendment? |  |
|  |  |  |  |
| **Amendment category** |  |
|  |
| **Amendment category 2 (if applicable)** |  |
|  |  |
| **Amendment category 3 (if applicable)** |  |
|  |  |  |  |
| **Description of changes** | Enter text |
|  |  |  |  |
| **Reason for changes** | Enter text |
|  |  |  |  |
| **Do the changes raise any ethical issues?** |  |
|  |  |
| **Do the changes raise any privacy (including data linkage) issues?**  |  |
|  |
| **If yes, provide description of ethical and/or privacy issues** | Enter text |
|  |  |
| **Does the amendment include additional/different drugs/devices or involve a new indication for any drug/device other than that approved in the original application?** |  |

## Radiation

|  |  |
| --- | --- |
| Does the amendment impact procedures involving radiation?  |  |
|  |  |  |
| **If yes, has the radiation risk category increased?** |  |
|  |
| *If the radiation risk category has increased, please submit a revised Medical Physicist Report in line with the* [*ARPANSA Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (RPS8)*](https://www.arpansa.gov.au/regulation-and-licensing/regulatory-publications/radiation-protection-series/codes-and-standards/rps8)*.*  |

## Participating Sites

|  |  |
| --- | --- |
| Does the amendment affect all sites approved by the reviewing HREC?  |  |
|  |
| **If no, list the sites which are affected** | Enter text |
|  |  |
| *An amendment to an ethically approved research project may also impact research governance/Site-Specific Assessment (SSA). The Research Governance Officer (RGO) at each affected site must be notified of the amendment by the site PI, in order to determine if research governance/SSA amendment is required.* |

## Supporting Departments (Governance Only)

|  |  |
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| Does the amendment impact the type or frequency of service provided by a supporting department at RMH? |  |
|  |
| **If yes, list departments** | Enter text |
|  |  |
| *Supporting departments may include: Anaesthesia, Anatomical pathology, Cardiology, Emergency, Haematology, Nuclear Medicine, Pharmacy, Radiology etc.* |

## Budget/Agreement Impacts (Governance Only)

Confirm if there are any RMH/MH Governance implications as a result of this amendment. E.g. are you requesting to add any new or additional samples, change the project duration, change the participant numbers etc.

**Please indicate if the amendment may have an impact on existing:**

|  |  |
| --- | --- |
| 1. RMH Agreements  |  |
|  |
| **2. RMH Departmental Statements of Approval (SoAs)** |  |
|  |  |
| **3. RMH Budget** |  |

If you have answered ‘YES’ to any of the above, you must also action the following:

1. Provide a simple but complete and informative table and written explanation clearly indicating what has changed and why in terms of $$$$/resources needed/budget changes.
2. This is in addition to filling in the amendment form and attaching any supporting paperwork from a sponsor or granting body.
3. This summary should clearly explain the financial difference between original approved budget and the new one - IN TOTAL i.e. what is the complete $$$ difference between old and new (not just a per patient costing) and what is the $$$ value of the new agreement.
4. Agreement variations should be accompanied as applicable by signed SoAs from every service department including one from the PI’s Head of Department.
5. Please include mar@mh.org.au in your amendment submission email.

**Amended Documents**

*Please ensure to provide both tracked and clean (final, untracked) versions of any revised documents.*

|  |  |
| --- | --- |
| Document title *(include version number, where applicable)* | Version Date  |
| Enter text |       |
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## Declaration

*To be completed by the Sponsor/CRO, or the Coordinating Principal Investigator (CPI) for a multi-site project, or the Principal Investigator (PI) for a single-site project.*

The information provided in this report is complete and correct. The project is being conducted in keeping with the conditions of approval of the reviewing HREC (and subject to any changes subsequently approved). The project is being conducted in compliance with the *National Statement on Ethical Conduct in Human Research (2007) updated 2018* and *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (2016)*, or as amended.

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Enter text | Email |       |
|  |
| **Organisation** | Enter text | **Telephone** |       |

|  |  |
| --- | --- |
| Signature |  |
|  |

|  |  |
| --- | --- |
| Date |       |