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| Project Amendment Form |
| Researchers are required to complete and submit this form to the Office for Research outlining project amendments for ethics approval and governance acknowledgementComplete this form to notify the Office for Research of the details of the amendment. Please refer to the [National Statement on Ethical Conduct in Human Research](https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72_national_statement_may_2015_150514_a.pdf), Sections 3.3.22 and 5.5 for advice on project amendments. |

## Instructions

Researchers are required to provide written details of project amendments to the SALHN Office for Research. The amendment notification process is a requirement of continuing ethics approval and institutional authorisation and aims to eliminate immediate risks to participants or to assist in the viability of recruitment or other research administration.

Please complete this form in conjunction with the Check list on page 4 then email completed form and updated documents to: Health.SALHNOfficeforResearch@sa.gov.au

**Please do not submit this amendment if the Site Specific Assessment form is under review or has not been authorised.**

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| **Date: Click here to enter text.** |
| **Office for Research reference number: Click here to enter text.** |
| **Application type:**[ ]  **Single site (SALHN only) – requires both ethics and governance review**[ ]  **Multi-site (SALHN Lead) requires both ethics and governance review**[ ]  **Multi-site (SALHN non-lead) – requires governance review only** |
| **Project Title: Click here to enter text.** |
| **Principal Investigator: Click here to enter text.** |

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| **Have there been previous amendments to this project?**[ ]  **Yes - Please provide a summary of amendments Click here to enter text.**[ ]  **No** |
| **Approval / Authorisation****Does this project have SAC HREC approval?** [ ]  **Yes - when does your SAC HREC approval expire? Click here to enter text.**[ ]  **No – when did your SAC HREC approval expire? Click here to enter text.****Does this project have governance authorisation?**[ ]  **Yes - please provide the authorisation date: Click here to enter text.**[ ]  **No**[ ]  **Pending** |

# Amendment details

**It is important to provide a detailed description on what is changing and why it is changing to assist the committee with the review of this amendment.**

**Clinical drug trials**

**For investigator Brochure and/or protocol amendments, please do not copy and paste the summary of changes into this document. The researchers should clearly explain the nature of the changes in lay terms.**

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| **Please provide detailed summary of the amendment:. Click here to enter text.** |
| **Please provide a reason for the changesClick here to enter text.** |
| Participants**How many participants have been recruited to date? Click here to enter text.****Do these changes create new risks for the participants?** [ ]  **Yes** [ ]  **No****If yes please outline the new risks, such as changes to confidentiality, physical or psychological risk, and increased time commitments: Click here to enter text.** |
| **If the study is approved by the SAC HREC, please list all approved study sites this amendment applies to: Click here to enter text.** |
| Conflicts of interest**Are there are any new or existing conflicts of interest that need to be declared?** **Please refer to Office for Research** [**Conflicts of Interest information sheet**](https://www.sahealth.sa.gov.au/wps/wcm/connect/20a6f3004baff93a9f01ff7c1f47d846/Conflicts%20of%20Interest%20SAC%20HREC%20Policy%20%28PDF%2093KB%29%20%28opens%20in%20a%20new%20window%29) **on the definition of a conflict of interest and how it needs to be disclosed and managed.**[ ]  **Yes – please provide details Click here to enter text.**[ ]  **No** |
| Investigator brochures and protocols **Have there been any changes to the IB for the following:**[ ]  **Yes** [ ]  **No - Has an explanatory statement been provided?**[ ]  **\*Yes** [ ]  **No - Does the PICF need to be updated?**[ ]  **\*Yes** [ ]  **No - Does the protocol need to be updated?**[ ]  **\*Yes** [ ]  **No - Is there any change to the participant safety?**[ ]  **Yes** [ ]  **No - Serious Adverse Events**[ ]  **Yes** [ ]  **No - Disease interactions**[ ]  **Yes** [ ]  **No - Drug interactions**[ ]  **Yes** [ ]  **No - Efficacy of the treatment****If yes to any of the above, please ensure updated details /documents have been provided and the changes are outlined in the explanatory statement on how these changes affect SALHN trial participants.** |

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| Office for Research fees**Non-Clinical trials (studies without one or more health-related intervention) do not incur fees in accordance with the** [SA Health Research Ethics and Governance Fees Schedule](https://www.sahealth.sa.gov.au/wps/wcm/connect/cb0325004782199699fefb2e504170d4/SA%2BHealth%2BFees%2BSchedule%2B2017-final.pdf?MOD=AJPERES&CACHEID=ROOTWORKSPACE-cb0325004782199699fefb2e504170d4-mbcgRdG)**. If you would like to request fees be waived or reduced for this study please fill in a** [Waiver of Fees application form](http://www.sahealth.sa.gov.au/wps/wcm/connect/public%2Bcontent/sa%2Bhealth%2Binternet/resources/reduction%2Bor%2Bwaiver%2Bof%2Bfees%2Brequest%2Bform%2B-%2Boffice%2Bfor%2Bresearch%2Bsalhn) **and include this with your submission documents.**  |
| Review fees**Are fees applicable to this research (based on the SA Health Fee Schedule)** [ ]  **Yes** [ ]  **No**[ ]  **Clinical trial with full sponsorship** [ ]  **Cooperative Research Group**[ ]  **Non commercially sponsored Clinical Trial**[ ]  **Health and Medical Research** **If your study is a clinical trial, are you requesting a reduction or waiver of ethics or governance fees?**[ ]  **Yes /** [ ]  **No**. |
| **DETAILS FOR INVOICING:** |
| ***This submission to SALHN may incur review fees (clinical trials only, fee waiver can be requested), in accordance with the SA Health ethics and governance fee schedule. The details provided below will be invoiced to the sponsor and should indicate who to address the invoice to.*****Please list invoice details below:**Sponsor/Institution Name:       Address 1       Suburb       Additional details to include in the invoice: |

## Please list all documents being submitted for the amendment.

**The details that you provide below will be replicated in the HREC approval and governance acknowledgement letter.**

**Please ensure all documents have updated version number and dates in the footer.**

**The updated HREA only needs to be signed by the Coordinating Principal Investigator.**

*
* **Declaration**

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| * I confirm the information provided in this form is true and correct.
* **Chief / Principal Investigator:** Click here to enter text.
* **Date**: Click here to enter text.
* **Signature**:
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# Checklist

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| SAC HREC is the lead committee | For RGO review only |
| * Please ensure all fields in this form are filled out.
* If appropriate, update the application form with the amendment details, using track changes.
	+ If the application form (i.e. LNR or HREA) is updated the listed investigators must re-sign the declarations on the last page of the application.
* Ensure your amended PICF (if required) is submitted with tracked changes and new version number and date in the footer.
* Please ensure all submitted documents have an updated version number and date in the footer.
* For multi-site applications, the master PICF is submitted to the SAC HREC and once approved, the site specific version (tracked and clean) to the RGO.
* Investigator brochures and protocols (for commercially sponsored trials)must be submitted with:
	+ An explanatory statement in the lay summary of this form, drawing attention to significant issues arising from IBs and with specific comments as to their significance and measures that do or do not need to be taken (such as PICF changes and updates to the protocols).
	+ A detailed summary of changes.
	+ A version showing tracked changes provided either by the Sponsor or Principal Investigator.
	+ Investigator brochures will not be accepted if they are password protected.
* Supply all other documents required to support the amendment.
* Sub study / extension study – prospective studies must be submitted as a new application and will not be accepted as an amendment.
 | * Please ensure all fields in this form are filled out.
* Please provide a copy of the HREC approval letter for the amendment
* Ensure your amended PICF (if required) is submitted with tracked changes and new version number and date in the footer.
* Please ensure all submitted documents have an updated version number and date in the footer.
* For multi-site applications, the master PICF is submitted to the lead HREC and once approved, the site specific version (tracked and clean) to the RGO.
* Investigator brochures and protocols (for commercially sponsored trials)must be submitted with:
	+ An explanatory statement in the lay summary of this form, drawing attention to significant issues arising from IBs and with specific comments as to their significance and measures that do or do not need to be taken (such as PICF changes and updates to the protocols).
	+ A detailed summary of changes.
	+ A version showing tracked changes provided either by the Sponsor or Principal Investigator.
	+ Investigator brochures will not be accepted if they are password protected.
* Supply all other documents required to support the amendment.
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