

Guidance and Checklist

Amendments and Novation Agreements

Overview

CALHN Research Services must review all Amendments/Variations and Novation agreements please email them to Health.CALHNClinicalTrials@sa.gov.au.

Please supply the following documents for review:

- Amendment/Variation/Novation agreement in word version
- HREC approval letter – if related to Protocol amendment or change of Principal Investigator (Amendment)
- Quotes – If adding any services/supporting departments not previously listed (Amendment)
- Effective date of change to new party (if a Novation agreement)
- HREC acknowledgement/approval of change of sponsor (if a Novation agreement)

Checklist	Yes	No
Is the Effective date of this Amendment/Novation the date of the last party to sign or the amendment commencement date ("Effective Date")?	<input type="checkbox"/>	<input type="checkbox"/>
Are the Parties to the Amendment/Novation listed upfront?	<input type="checkbox"/>	<input type="checkbox"/>
Is the Institution Party name in the Amendment/Novation as below? Central Adelaide Local Health Network Incorporated ABN 96 269 526 412 Level 10, Roma Mitchell House 136 North Terrace, Adelaide, SA 5000	<input type="checkbox"/>	<input type="checkbox"/>
Are there any terms such as "on behalf of", "acting for" or "representing"? These are unacceptable as they imply an agency relationship. Each Party must act and sign in its own right.	<input type="checkbox"/>	<input type="checkbox"/>
Has the Principal Investigator been listed as a Party to the Amendment/Novation? This is not permitted. The Principal Investigator is an employee of CALHN and does not have the authorisation to be a party to the agreement.	<input type="checkbox"/>	<input type="checkbox"/>
Is the Study name and Protocol listed? If not, these must be included to identify the Study.	<input type="checkbox"/>	<input type="checkbox"/>
Do the recitals include that the Sponsor and Institution are Parties to a Clinical Trial Research Agreement dated XX XXX XX ("Agreement") for the above named Study?	<input type="checkbox"/>	<input type="checkbox"/>
If there has already been an amendment, do the recitals include that the Sponsor and the Institution are Parties to a Clinical Trial Research Agreement dated XX XXX XX and an Amendment agreement dated XX XXX XX (collectively termed "Agreement") for the above named Study?	<input type="checkbox"/>	<input type="checkbox"/>
Are the changed terms of the Clinical Trial Research Agreement acceptable?	<input type="checkbox"/>	<input type="checkbox"/>
Are there any changes to the indemnity or insurance clauses? If so, notify CALHN Research Services.	<input type="checkbox"/>	<input type="checkbox"/>
Is there a clause indicating that all other conditions apply such as, "Except as provided herein, all other terms and conditions of the Agreement shall remain in full force and effect."	<input type="checkbox"/>	<input type="checkbox"/>
Is there an execution section for each of the Parties?	<input type="checkbox"/>	<input type="checkbox"/>
Is the execution section for the Principal Investigator prefaced with, "Read and acknowledged by the Principal Investigator"? The words, "Agreed and accepted" are <u>not</u> appropriate as they imply the Principal Investigator is a Party and thus, personally liable. It is SA Health's policy, based on our insurer's requirements, that investigators, as employees of Local Health Network's within South Australia, are not contractual parties to such agreements.	<input type="checkbox"/>	<input type="checkbox"/>