

CENTRAL COAST LOCAL HEALTH DISTRICT (CCLHD) *Amendment Form (AF) - Site Specific Assessment (SSA)* National Ethics Application Form (NEAF) and Low/Negligible Risk Research (LNR) Form

Instructions for submission:

1. A cover letter is not required with this form.
2. This form is to be used for all notifications of Amendments to NEAF and LNR Applications being undertaken at a CCLHD site and for amendments to legal documentation (including Research Agreements, updated Certificates of Currency, Forms of Indemnity and Clinical Trial Notification/Exemption Forms) specific to a CCLHD site.
3. The approving Lead NSW Human Research Ethics Committee (HREC) must be notified first of any amendment/s to a research project and should approve any request/s before notification is submitted to the Research Governance Officer (RGO), CCLHD. It is recommended that the approving HREC be contacted for advice on their individual requirements as these vary between HRECs.
Please note that updated legal documentation would be a Site Specific request and would therefore not require approval by an HREC only the RGO of CCLHD. The RGO for CCLHD is the Research Manager.
4. Please complete this form electronically before printing for signing, please submit in hard copy.
A copy of the form is required for each project which this amendment applies to.
5. Please provide clean versions of all the amended document/s with updated version/dates.
6. Please ensure the following is submitted:
 - 1 copy of the HREC Approval Letter
 - 1 Master copy of each HREC approved document/s listed on the HREC Amendment Approval letter.
 - 1 Site specific copy of each HREC approved documents listed on the HREC Amendment Approval letter.

Please note that requests for changes in personnel must be submitted using the 'CCLHD- SSA- Change in Personnel Form'- not this form.

Information to note:

- The HREC approval letter must be attached to all notifications along with a copy of all amended documentation unless the Amendment is for updated legal documentation.
- This form is to be used for applications where the SSA has been originally approved by the CCLHD after the 11th February 2013. Any Amendments for SSA's approved or submitted to the Northern Sydney Local Health District (NSLHD) Research Office prior to this date will require submission directly to NSLHD. Please see the NSLHD Research Office webpage for application requirements;
<http://www.northernsydneyresearch.com.au/>
- Once approved and signed by the Research Manager this form will be returned in the post.
An approval letter will not be issued along with this form.

Contact details for enquiries relating to this notification of Amendment:

[Name]
[Address]
[email]
[phone]

The following document should be submitted to:

**AMANDA JACKSON, RESEARCH MANAGER, LEVEL 6,
WEST WING, GOSFORD HOSPITAL, HOLDEN ST, GOSFORD NSW 2250**

FOR FURTHER ADVICE PLEASE CONTACT AMANDA JACKSON

PH:(02) 4320 3218

MOB: 0417 452 746

E-MAIL: c cresearch@nscchahs.health.nsw.gov.au

CCLHD- SSA NEAF & LNR- Amendment Form

Author: Amanda Jackson

Version Number: 1

Version Date: 3rd April 2013

Amendment Notification Form

CCLHD Protocol No:													
AURED HREC Ref No:													
Name of HREC:													
HREC Local Reference Number:													
Please list the Central Coast Health Sites for which this amendment applies to:	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #d9ead3;"> <th colspan="2" style="text-align: left;">Central Coast LHD</th> </tr> <tr> <th style="text-align: left;">Site Name</th> <th style="text-align: left;">SSA Reference No</th> </tr> </thead> <tbody> <tr> <td><input type="checkbox"/> Gosford</td> <td></td> </tr> <tr> <td><input type="checkbox"/> Wyong</td> <td></td> </tr> <tr> <td><input type="checkbox"/> Woy Woy</td> <td></td> </tr> <tr> <td><input type="checkbox"/> Long Jetty</td> <td></td> </tr> </tbody> </table>	Central Coast LHD		Site Name	SSA Reference No	<input type="checkbox"/> Gosford		<input type="checkbox"/> Wyong		<input type="checkbox"/> Woy Woy		<input type="checkbox"/> Long Jetty	
Central Coast LHD													
Site Name	SSA Reference No												
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<input type="checkbox"/> Woy Woy													
<input type="checkbox"/> Long Jetty													
Please attach a copy of the HREC amendment approval letter. <i>Please note this is not applicable for updated legal documentation</i>	N/A <input type="checkbox"/> Attached <input type="checkbox"/> Date of Approval: _____												
Please attach a copy of the Master Patient Information Sheet and Consent Form if applicable to this amendment	N/A <input type="checkbox"/> Attached <input type="checkbox"/> Version No: _____ Version Date: _____												
Please attach a copy of the Site Specific Patient Information Sheet and Consent Form if applicable to this amendment	N/A <input type="checkbox"/> Attached <input type="checkbox"/> Version No: _____ Version Date: _____												
Documentation being submitted for Acknowledgement by the RGO: <i>Please provide a list of all documentation to be listed on the amendment acknowledgement letter including Version numbers and dates (excluding any participant information sheets listed above or legal documentation below).</i>	1. _____ 2. _____ 3. _____ 4. _____ 5. _____												
Does the amendment require the TGA CTN form to be amended? <i>If so please attach a CTN form signed by the Lead HREC.</i>	N/A <input type="checkbox"/> Attached <input type="checkbox"/>												
Does the amendment require changes to the Clinical Trial Research Agreement (CTRA)? <i>If so please attach a copy of the CTRA and a summary of changes for review. Please note that any changes to the standard wording of a Medicines Australia or Medicines Technology Association Australia (MTAA) Clinical Trial Agreement should first be approved by the by the Office of Health and Medical Research (OHMR). If these have not been previously approved these will be sent by CCLHD to the OHMRs preferred legal advisor for review at the sponsor/funders own cost.</i>	N/A <input type="checkbox"/> Attached <input type="checkbox"/>												
Does the amendment require an updated Form of Indemnity (Fol)? <i>If so please attach a copy of the Fol , this should be in the Standard Medicines Australia format.</i>	N/A <input type="checkbox"/> Attached <input type="checkbox"/>												
Does the amendment require an updated Certificate of Currency (CoC)? <i>If so please attach a copy of the CoC.</i>	N/A <input type="checkbox"/> Attached <input type="checkbox"/> Expiry Date: _____												