

Guidance and Checklist - Confidentiality Agreements

Overview

Wherever possible, Confidentiality Agreements (CDAs) should be mutual (i.e. all parties will be sharing confidential information). This is in order to protect any Central Adelaide Local Health Network Incorporated (CALHN) confidential information that may be shared with the Clinical Research Organisation (CRO) and/or the study Sponsor.

Non-study specific mutual CDAs exist with a number of Sponsors/CROs, until a list of these companies has been finalised, please check with the CALHN Research Services to ascertain whether a mutual agreement is in place.

CALHN Research Services must review all CDAs, please email them to: Health.CALHNClinicalTrials@sa.gov.au.

Checklist

Checklist	Yes	No
Is the CDA mutual? If NO: Please ask the CRO/Sponsor who provided the CDA if they have a mutual CDA template (the CALHN Research Services supports the use of mutual CDAs, and it is requested that where possible this template should be used).	<input type="checkbox"/>	<input type="checkbox"/>
Is the Effective date of this agreement the date of the last party to sign ("Effective Date")	<input type="checkbox"/>	<input type="checkbox"/>
Are the Parties to the CDA listed upfront?	<input type="checkbox"/>	<input type="checkbox"/>
Has the Principal Investigator (PI) been listed as a Party to the CDA? This is not permitted. The PI is an employee of CALHN and does not have the authorisation to be a party to the agreement. Please ask the CRO/Sponsor who provided the CDA if they have a CDA template for contracting with the Institution rather than the PI.	<input type="checkbox"/>	<input type="checkbox"/>
Will this be a multi-site CALHN study within South Australia? If the TQEH and RAH are both potential study sites, then one CDA can cover both sites. Similarly, as SA Pathology and SA Pharmacy are entities of CALHN they are also covered under this agreement.	<input type="checkbox"/>	<input type="checkbox"/>
Is the Institution Party name: 'Central Adelaide Local Health Network Incorporated (ABN 96 269 526 412)'? Also refer to the document "Parties and Signatories to a CALHN Research Agreement" available for download on the website here for further details on contracting parties.	<input type="checkbox"/>	<input type="checkbox"/>
If the CRO is acting on behalf of a sponsor - Is there a clause indicating that the Institution agrees that a sponsor will be a "third party beneficiary" If a sponsor wishes to have the right to enforce the obligations of the CDA, it must be a party to the CDA.	<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"/>