

ELECTRONIC SIGNING OF LOW & NEGLIGIBLE RISK SITE SPECIFIC APPLICATIONS IN RESEARCH GOVERNANCE

PROCEDURE[®]

DOCUMENT SUMMARY/KEY POINTS

This standard operating procedure will ensure a consistent approach is applied in the signature process during submission, review and approval of Low and Negligible Risk site specific application for Human Research across SCHN.

CHANGE SUMMARY

- N/A- New Procedure

READ ACKNOWLEDGEMENT

- All SCHN researchers/investigators should read and acknowledge they understand the contents of this document

Approved by:	SCHN Policy, Procedure and Guideline Committee	
Date Effective:	1 st November 2015	Review Period: 3 years
Team Leader:	Research Governance Officer	Area/Dept: Research Governance

1 Purpose & Scope

The aim of this document is to outline the acceptable ways for signing documents electronically as equivalent to handwritten signatures for submission, review and authorisation of site specific applications. Electronic signatures will be accepted and used in place of handwritten signatures.

2 Definitions and abbreviations

2.1 Abbreviations

CHW	The Children's Hospital at Westmead
CTRA	Clinical Trial Research Agreements
HREC	Human Research Ethics Committee
LNRSSA	Low and Negligible Risk Site Specific Assessment
NEAF	National Ethics Application Form
NETS	Newborn and Paediatric Emergency Transport Service
PSN	Pregnancy and Newborn Services Network
RGAA	Research Governance Administration Assistant
RGO	Research Governance Officer
SCH	Sydney Children's Hospital
SOP	Standard Operating Procedure
SSA	Site Specific Assessment

2.2 Definitions

Electronic signatures: are simply electronic confirmations of identity. This definition is deliberately broad enough to encompass all forms of electronic identification, from biometric signatures such as iris scans and fingerprints to non-biometric signatures, such as digital signatures¹. Electronic Transactions Acts at the Federal and State levels in Australia recognise electronic signatures without setting any technology specific conditions^{2, 3}. Electronic signatures must serve the same essential functions that we expect of documents signed by handwritten signatures, namely integrity, non-repudiation, authentication and confidentiality. In the digital realm, integrity means ensuring that a communication has not been altered in the course of transmission. It is concerned with the accuracy and completeness of the communication. The recipient of an electronic communication must be confident of a communication's integrity before she can rely on and act on the communication¹.

Handwritten signatures: traditional paper-based handwritten signature is any mark that has been affixed by the signer with the intent to be bound by the contents of the document. Once

affixed, the signature and the document becomes one composite thing. This encapsulates an awareness of the terms above the signature, agreement to be bound by those same terms, knowledge of consequence of breach, awareness that the signature is non-repudiable as a sign of intent, and providing an unalterable permanent record of event ¹.

Online Forms: The Online Forms website is an online system that enables users to complete their applications for research ethics and governance review electronically. The website hosts a licensed copy of the NHMRC's NEAF, as well as the site specific assessment forms for the public health systems of New South Wales, Queensland, South Australia and Victoria. www.ethicsform.org/au/SignIn.aspx

Principal Investigator: is the individual who takes responsibility for the overall conduct, management, monitoring and reporting of research conducted at a site and submits the research project for site authorisation.

Research Governance Officer: is the individual appointed within the Public Health Organisation who is responsible for the management of applications for site authorisation and oversight of authorised research projects.

Site authorisation: is the authorisation granted by the Chief Executive or delegate of the Public Health Organisation for the commencement of a research project.

LNR Site-specific assessment: is a mechanism used by Public Health Organisations to ensure that the proposed research project complies with minimum governance requirements, and to consider whether the research should be conducted and supported at the proposed site.

3 Forms of accepted electronic signatures for site specific applications

3.1 Online Forms generated

The Online Forms website gives the capacity to sign LNRSSA/SSA declaration forms electronically by sending a request for authorisation via e-mail to the designated authority including investigators (declaration A), head of departments (declaration B), head of supporting departments (declaration C) and nominated authority for data provision (declaration D).

- **To create an Online Forms account:** A log in account will be required in order to be able to authorise the forms electronically. Use the following link to create an account in Online Forms: [Online Forms | Create Account](#)

- **To obtain electronic authorisation:**

Detailed instructions of how to use the system for electronic authorisation can be accessed through the following link which demonstrates step-by- step:

- How To Obtain Electronic Authorisations
- How to sign an electronic authorisation request

<https://au.ethicsform.org/Help/Demos/DemoElectronicAuthorisations.aspx>

3.2 Adobe signed declaration forms

An alternative acceptable form of electronic signatures is by signing declaration forms using Adobe Reader tools.

Note: This method is useful in obtaining signatures required for amendment submissions where declaration A and/or B might be required.

- **To obtain electronic signatures:**

1. After completing the SSA form on Online Forms, generate a submission code for the application.
2. Create a PDF final version of the application.
3. Obtain the relevant signatures by e-mailing the declaration form to signatory in PDF format. Signatory can insert digital signature using Adobe Reader Tab: "Sign" followed by selecting "Place Signature".

Note: In absence of access to Adobe Reader tools, scanned handwritten signatures will be accepted in PDF format.

- You can download separate declaration forms from the research governance intranet site using the following link - "Forms":

<http://intranet.schn.health.nsw.gov.au/research/research-governance>

4 Acquiring Research Governance Authorisation (Declaration E)

Submit the LNRSSA application (signed by either forms mentioned above) and supporting documents electronically to the governance inbox: governance.schn@health.nsw.gov.au as per [research governance SSA Submission guidelines](#) .

- All submissions and correspondences must be sent from a **valid email address** linked to the contact person's organisation. Submissions from public e-mail addresses provided by a public email domain (such as: AOL; Gmail; Hotmail; Live; Yahoo) will not be accepted (In transition - to be enforced starting 1/01/2016)
- The Principal Investigator **must be** cc'd on all submissions

5 References

1. Australasian Legal Information Institute- Digital Signature, Certification Authorities and the Law - [2002] MurUEJL 29
2. Electronic Transactions Act 1999 - C2011C00445
3. Electronic Transactions Act 2000 (NSW) No 8, Part 2, Division 2 Section 9 for signature requirements

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