The North Coast NSW Human Research Ethics Committee (NCNSW HREC) provides scientific and ethical review of human research ethics applications for research that takes place within institutions governed by Northern New South Wales (NNSW) and/or Mid North Coast (MNC) Local Health Districts (LHDs); and/or external institutions/organisations and/or for research that is undertaken by independent researchers within the geographical boundaries of NNSW and MNC LHDs as approved by the HREC Chairperson.

Please use the following checklist to ensure your application meets the minimum submission requirements to be deemed eligible for review by the HREC. IMPORTANT: Failure to complete and upload this checklist will result in the application being deemed ineligible, requiring a revised submission which could delay study commencement.

Submitting a new ethics application to the NCNSW HREC requires the following elements:

* A Human Research Ethics Application (HREA) completed in the Research Ethics Governance Information System ([REGIS](https://regis.health.nsw.gov.au/)) including:
	+ all study documents – e.g., study protocol, participant information sheet and consent form, etc; AND
	+ this completed checklist.

Check each box below to confirm completion of the associated action and submit this checklist with the HREA Application via REGIS. If you need assistance, please email the Executive Officer, NCNSW HREC:
NNSWLHD-Ethics@health.nsw.gov.au

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| 1.  | **Ethical Review Pathway**All research conducted within NNSW and/or the MNC LHDs involving participants (e.g., patients, including their health information, or health service employees) must undergo ethical and scientific review and obtain approval before commencing (see [NSW Health Policy Directive PD2010\_055](https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2010_055) and Section 5 of [the National Statement](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023)). This review ensures research is conducted in accordance with the National Health and Medical Research Council (NHMRC) *National Statement on Ethical Conduct in Human Research* ([the National Statement](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023)).Depending on the size and type of your research activity, ethical approval can be obtained from the following HRECs: * single-site within NNSW or MNC LHDs from the [**North Coast NSW HREC**](https://nnswlhd.health.nsw.gov.au/our-organisation/research/research-governance/tnc-nsw-human-research-ethics-committee),
* multiple-sites within NSW from a [**‘Certified NSW HREC’**](https://www.medicalresearch.nsw.gov.au/ethics-governance-contacts/), or
* multiple-sites nationwide from a [**‘Certified HREC’**](https://www.nhmrc.gov.au/sites/default/files/documents/attachments/List%20of%20certified%20institutions_Final.pdf)under the [**National Mutual Acceptance**](https://www.medicalresearch.nsw.gov.au/national-mutual-acceptance/)

If the study is to be led by an employee or agent of NNSW and/or MNC LHD staff and the study poses no risk of harm or discomfort (see Chapter 2.1 of [the National Statement](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023)) there is a non-HREC review process for ethical review which serves the same purpose as HREC review (see Chapters 5.1.12 to 5.1.14 and 5.1.17 [the National Statement](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023)). Where appropriate, this is the preferred ethical review pathway, as it is more efficient for all parties. This is an institutional decision so if you consider this may be suitable, please review the relevant application criteria: * [Northern NSW Local Health District](https://nnswlhd.health.nsw.gov.au/our-organisation/research/research-governance/preparing-a-governance-application-ssa) (see section “Quality Activities”)
* [Mid North Coast Local Health District](https://int.mnclhd.health.nsw.gov.au/research-and-knowledge-translation/forms-and-resources/) (see section “Quality Project Registration Form”)

**I have read the advice above and confirm the NCNSW HREC review is most appropriate.**[ ]   |
| 2.  | **Correct Site/s and Principal Investigators Nominated**At REGIS Project Registration, the site/s and associated Principal Investigators (PI), who will have responsibility for the conduct/management of the study at the site, are named. In most instances the PI is an employee/agent of the LHD. Before the HREA is submitted for review, please ensure this information is correct. Incorrect naming of sites and/or investigators will result in the HREA being returned to you for amendment and may delay study site authorisation.When conducting research across more than one site within the same LHD (e.g. hospitals), it may be more efficient to instead name the LHD as the site. If you are unsure about whether the named PI and/or site may be appropriate, please consult with the relevant Research Governance Officer (contact details below) to confirm. **I have read the advice above and confirm the Principal Investigator/s and site/s named are correct.**[ ]   |
| 3. | **Study Material** The NCNSW HREC requires that all HREAs are submitted using the **NCNSW HREC approved templates,** including the study protocol and (where relevant) a Participant Information Sheet and Consent Form. See: [NCNSW HREC Resources and Forms](https://nnswlhd.health.nsw.gov.au/our-organisation/research/research-governance/resources-forms)In addition, ensure you submit all relevant study material including (but not limited to): * **Recruitment Invitations** such as letter/email, telephone script, text message script etc.
* **Survey Tools / Questionnaires**
* **Semi-Structured Interview Questions**
* **Focus Group Prompts**
* **Recruitment Advertisements / Flyers**

Please ensure relevant study documents appropriately include a pre-amble and post-amble providing the potential participant information necessary to inform their decision on whether to participate (e.g. survey tool, interview questions, focus group prompts). [ ]  **I have read the advice above and confirm the submission includes a Protocol using the NCNSW HREC Template and (where relevant) Participant Information Sheet and Consent Form and all other relevant study material.** |
| 4.  | **NSW eHealth Supported Platforms**Please ensure compliance with the [eHealth Video Conferencing Platforms Guidelines](https://intranet.hss.health.nsw.gov.au/__data/assets/pdf_file/0011/1343819/Video-Conferencing-Platforms-Guidelines.pdf). Note: Microsoft Teams and Pexip are the preferred options. Zoom is not to be used for sharing confidential information. Online Survey Platforms are generally ethically acceptable and there is no preferred platform (e.g. QARS, REDcap, Qualtrics). Please note some platforms are not accessible on the NSW Health network (e.g. Google Forms). SurveyMonkey is acceptable, however it is important to inform potential participants (via Participant Information Sheet and/or Survey Introductory Pre-amble) that data are stored in servers hosted in the United States of America and are subject to privacy laws of that country. Please see the following guidance provided by the NSW Education Standard Authority (NESA; [SurveyMonkey Privacy Notice](https://educationstandards.nsw.edu.au/wps/portal/nesa/about/who-we-are/privacy/survey-monkey-privacy-notice)) for guidance. **I have read the advice above and confirm NSW eHealth Supported Platforms have been utilised.**[ ]  |
| 5.  | **Scientific Merit, Study Design and Supervision Expectations**The NCNSW HREC will consider the ethical and scientific merits of the HREA and expects that if the CPI does not have the necessary research experience or knowledge, they will conduct their research under supervision (clinical and/or academic) and engage an expert for statistical analysis and other specialists where appropriate (e.g. health economists). Statisticians, supervisors and other research experts should be named in the HREA and Protocol and be engaged with the research prior to HREA submission. This is particularly relevant to data analysis (it is not adequate to propose consultation with a statistician once data has been collected). They should be engaged at the planning and methodology stages). It is expected supervisors are actively involved in the study design and have reviewed the HREA prior to submission. [ ] **I have read the advice above and confirm the research team have been engaged in the study design and (where relevant) my supervisor has review the HREA, protocol and related study material.** |
| 6.  | **Document Management** **Study document naming conventions.** Please adopt meaningful and practical study document naming conventions and version control including the following guidance: * Files should be named consistently
* File names should be short but descriptive (<25 characters)
* Avoid special characters (\*, %) or spaces in a file name
* Use capitals and underscores instead of periods or spaces or slashes
* Use date format ISO 8601: YYYYMMDD
* Include a version number
* Write down naming convention in data management plan

For example, “StudyProtocol\_v2\_2023-07-02”, “PIS\_Staff\_Interviews\_v1\_2023-07-02”. NOTE: In REGIS, the “Document Descriptor" should employ the same logic as this is how it will be listed on the approval notification.**Study document version control.** Please include the document title and version control in the footer of all study documents. The version control should reflect, in an iterative manner, the versions reviewed by the HREC in successive order. For example, in the initial submission, all study documents will be version 1. Once the documents have been edited, the document becomes version 2 (v2), and this is updated in the document title and document footer. [ ] **I have read the advice above and confirm the study documents submitted have a document title, REGIS document description, and embedded version control as described above.** |

Once your HREA has been submitted, you can expect an email stating whether your application has been deemed eligible for review by the HREC.

**Meeting dates and submission deadlines are as follows:**

Please note: the Executive Committee may only review lower risk research and the NCNSW HREC can review both lower risk research and higher risk research HREC. Please see Chapter 2.1 of [the National Statement](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023) for further guidance on risk profiles of research.

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| **Submission Deadline****(Thurs)** | **Meeting Date****(Thurs)** | **Committee** |
| 4 JAN 24 | 18 JAN 24 | NCNSW HREC |
| 25 JAN 24 | 1 FEB 24 | Executive Committee  |
| 1 FEB 24 | 15 FEB 24 | NCNSW HREC |
| 15 FEB 24 | 29 FEB 24 | Executive Committee |
| 29 FEB 24 | 14 MAR 24 | NCNSW HREC |
| 14 MAR 24 | 28 MAR 24 | Executive Committee |
| 28 MAR 24 | 11 APR 24 | NCNSW HREC |
| 17 APR 24 | WED 24 APR 24 | Executive Committee |
| 25 APR 24 | 9 MAY 24 | NCNSW HREC |
| 9 MAY 24 | 23 MAY 24 | Executive Committee |
| 29 MAY 24 | 6 JUN 24 | NCNSW HREC |
| 6 JUN 24 | 20 JUN 24 | Executive Committee |
| 20 JUN 24 | 4 JUL 24 | NCNSW HREC |
| 4 JUL 24 | 18 JUL 24 | Executive Committee |
| 18 JUL 24 | 1 AUG 24 | NCNSW HREC |
| 1 AUG 24 | 15 AUG 24 | Executive Committee |
| 15 AUG 24 | 29 AUG 24 | NCNSW HREC |
| 29 AUG 24 | 12 SEP 24 | Executive Committee |
| 12 SEP 24 | 26 SEP 24 | NCNSW HREC |
| 26 SEP 24 | 10 OCT 24 | Exec Comm |
| 10 OCT 24 | 24 OCT 24 | NCNSW HREC |
| 24 OCT 24 | 7 NOV 24 | Exec Comm |
| 7 NOV 24 | 21 NOV 24 | NCNSW HREC |
| 21 NOV 24 | 5 DEC 24 | Exec Comm |
| 5 DEC 24 | 19 DEC 24 | NCNSW HREC |

**Contacts:**

If you need assistance with your application please email the Executive Officer, NCNSW HREC:

NNSWLHD-Ethics@health.nsw.gov.au

If you need assistance with your study design, or you wish to discuss research collaboration, please see the following contact lists:

[Northern NSW Local Health District](https://nnswlhd.health.nsw.gov.au/our-organisation/research/research-support/contact-us)

[Mid North Coast Local Health District](https://mnclhd.health.nsw.gov.au/research/about-us/)

Research Governance Officer, NNSWLHD: NNSWLHD-ResearchGovernance@health.nsw.gov.au

Research Governance Officer, MNCLHD: MNCLHD-RGO@health.nsw.gov.au