**Human Research Ethics Committee   
of the Northern Territory Department of Health   
and Menzies School of Health Research**

# OFFICE USE ONLY

# Project ID Number:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**FORM FOR LOW RISK CLINICAL AUDITS, QUALITY ASSURANCE, and CASE STUDIES**

***INSTRUCTIONS:***

***Scope:*** *This form is ONLY to be used for clinical audits, clinical quality assurance activities, and clinical case studies using data collected during standard care that will be de-identified with no deviation from standard care and no human interaction. Other low risk studies e.g. some program evaluations or multi-dataset analyses should use the full HREC Application Form and might be eligible for expedited review. Studies that involve patient participation beyond standard care should use the full HREC Application Form.*

*Ethics clearance forms for Audits, QAs and Case Studies may be submitted at any time and are not limited to specific deadlines.*

|  |  |  |
| --- | --- | --- |
| **1. PROJECT TITLE**  (*A title that indicates the area of clinical activity to be audited. The title should be informative.)* | | |
|  | | |
| **2. PROJECT CLASSIFICATION** | | |
| *Will the project describe or analyse routine clinical care, or the data obtained from routine care, such as to determine adherence to guidelines or standard clinical practice, or to record the results of routine care?*  *AND*  *Is the risk that individuals may be identified in reports or publications resulting from this investigation considered to be negligible?* | *Yes* | *No\** |
| *Is the investigation a retrospective case study consisting of analysis of data concerning participant(s) that were treated under routine clinical care according to national guidelines and agreements and not subject to experimental or new protocols or primary research?*  *AND*  *Is the risk that individuals may be identified in reports or publications resulting from this investigation considered to be negligible?* | *Yes* | *No\** |
| \* If NO to both of the above, please do not proceed with this form. All other research should be submitted for review using the full HREC Application Form. Other low risk research may be subject to expedited review after submission of the full HREC application form. For NT Health RGO requirements, please go to <https://health.nt.gov.au/data-and-research/nt-health-research/research-governance2> | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **PROJECT INFORMATION\*** | | | | |
| **3. INVESTIGATORS** | **Position** | **Department and Organisation** | **Contact Details** | **Signature** |
| ***NAME*** *of Principal Investigator  (\*Student’s supervisor, if applicable)* |  |  | *Ph (W):*  *Ph (Mob):*  *Email:*  *Postal Address:* |  |
| *\* Students including advanced trainees, registrars, medical students, and higher degree candidates should be identified as Co-investigators below and not as Principal Investigator.* | | | | |
| *Name of Co- Investigator/Student:* |  |  | *Ph (W):*  *Ph (Mob):*  *Email:*  *Postal Address:* |  |
| *Name of Co-Investigator/Student:* |  |  | *Ph (W):*  *Ph (Mob):*  *Email:*  *Postal Address:* |  |
| *Name of Co-Investigator/Student:* |  |  | *Ph (W):*  *Ph (Mob):*  *Email:*  *Postal Address:* |  |

|  |
| --- |
| **4. STUDY SITES (Please mark as applicable)** |
| *Top End Region:  Royal Darwin Hospital  Palmerston Regional Hospital*  *Primary Health Care (PHC)  Mental Health and Alcohol Other Drugs (MHAOD)*  *Big Rivers Region:  Katherine Hospital  PHC MHAOD*  *East Arnhem Region:  Gove District Hospital  PHC MHAOD*  *Central Australia Region:  Alice Springs Hospital  PHC MHAOD*  *Barkly Region:  Tenant Creek Hospital  PHC MHAOD*  *Other (please specify)      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* |
| **5. PERIOD FOR WHICH APPROVAL IS SOUGHT**  Proposed project start date:  Expected completion date (Please allow at least 6 months):  Date range of collected data (eg Jan 2011 to Dec 2021): |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 6. RESEARCH CATEGORIES | | | | |
| *(Please tick applicable boxes)* | *Targeted* | | *Incidental* | |
| *Aboriginal and Torres Strait Islander people* |  | |  | |
| *Women who are pregnant and/or the human foetus* |  | |  | |
| *Children and young people* |  | |  | |
| *People with a cognitive impairment, an intellectual disability, or a mental illness* |  | |  | |
| *People who may be involved in illegal activities* |  | |  | |
| *People in dependent or unequal relationships* |  | |  | |
| *People highly dependent on medical care who may be unable to give consent* |  | |  | |
| *People in other countries* |  | |  | |
| 7. AUDIT / CASE STUDY DETAILS | | | | |
| *7.1. A brief description of the area to be audited or presented as a case study.* *Please ensure that the purpose and justification for the study are clearly described. A brief literature review and reference list should be included.* | | | | |
| *7.2. A statement of the standards the team is intending to relate their practice to. (The statement does not have to contain the standards themselves, only sufficient information to indicate that such standards exist and how to locate them, if required e.g. Acute Coronary Syndromes Clinical Care Standard).* | | | | |
| 7.3. How the audit will be conducted? (Retrospectively or prospectively, using what kinds of information?) | | | | |
| *7.4 Does the proposal involve randomisation or the use of a control group or a placebo? (If YES, then please submit the HREC Application Form and RGO site specific assessment (SSA) Form - not this form.)*  *(Proposals involving comparison with published or prior treatment results with other groups are acceptable.)* | | *Yes* | | *No* |
| *7.5 Does the proposal involve any alteration to routine clinical care provided to participants or seek to gather information of a nature more extensive than that collected during routine clinical care?  (If YES, then please submit the HREC Application Form and RGO SSA Form - not this form.)* | | *Yes* | | *No* |
| *7.6 Does the research pose greater than negligible risk to participants, i.e., Is there a foreseeable effect on participants or risk to participants as a result of the research that is different from any effect resulting from normal clinical management and is any foreseeable risk more than one of inconvenience? (e.g. physical, psychological, spiritual, or social, which could cause distress, stigmatisation or discrimination.)*  *If YES, then please submit the full HREC Application Form and RGO SSA Form - not this form.)*  *Please note that this refers only to risks directly related to the research component and not to risks which the participants would necessarily have been exposed to as part of effective standard care.* | | *Yes* | | *No* |
| **8. CONFIDENTIALITY, DATA COLLECTION AND STORAGE**  *Reference may be made to the NT Information Act and Information Privacy Principles (*[*https://infocomm.nt.gov.au*](https://infocomm.nt.gov.au)*), and the NHMRC ‘Guidelines approved under Section 95 and 95A of the Privacy Act 1988.* | | | | |
| *8.1 How many records/cases are expected to be analysed?* | | | | |
| 8.2 Will consent be obtained from participants?  If YES, how will consent be obtained?  If NO, why not? | | *Yes* | | *No* |
| 8.3 (a) Please describe the protocol for acquiring, processing and storing data and describe who will acquire the data and how permission was or will be gained for them to acquire the data. (This means that you certify that the protocol will comply with the IPPs and relevant Territory and Australian legislation.) Data should be stored preferably in a password protected secure network drive folder accessible by the study team members. | | | | |
| 8.3 (b) Please list/describe the data fields to be accessed and analysed (a separate page may be attached if necessary). Please only include relevant data points that are required to fulfil the purpose of the audit or to answer the research question. | | | | |
| 8.4 Is the original data: (Please refer to Chapter 3.1 of the National Statement on Ethical Conduct in Human Research)  Identifiable  Re-identifiable  Non-identifiable | | | | |
| *8.5 Will the data be de-identified?* | | *Yes* | | *No* |
| 8.5 (a) In particular please state whether it will be possible or likely to identify participants or Aboriginal Communities from data that you will use. The usual method to prevent this is to remove permanently any information that could allow identification. | | | | |
| 8.5 (b) If it would be possible to identify participants or communities, please detail how the data will be protected from release or access. | | | | |
| *8.6 Storage of data and security*  *Please* *indicate where data including hardcopies and electronic files will be stored, who will have access, and how and when it will be destroyed. Data should be stored preferably in a password protected secure network drive folder accessible by the study team members for a minimum storage time of 5 years.* | | | | |
| **9. DATA ANALYSIS and IMPACT** | | | | |
| *9.1 Please describe the protocol for data analysis e.g. Statistical Analysis (Inferential or Descriptive Analysis); Diagnostic Analysis; Predictive Analysis; or Prescriptive Analysis. Please give a clear and detailed explanation of how the data will be analysed.* | | | | |
| *9.2 How will the results of the investigation be disseminated and to whom?* | | | | |
| *9.3 How will the impact of the audit be monitored?* | | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **10. ORGANISATIONAL ENDORSEMENTS FOR NON-NT HEALTH STUDIES**  *The completed signed form should be submitted by email directly to the ethics office for expedited review* [***NTHREC@menzies.edu.au***](mailto:NTHREC@menzies.edu.au) | | | |
| **Name of organisation where research is to be conducted:** | | | |
| ***The following endorsements are required*** | | | |
|  | Name | Signature | Date |
| PI’s Supervisor: |  |  |  |
| Organisational Head or Delegate: |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **11. ORGANISATIONAL ENDORSEMENTS FOR STUDIES CONDUCTED WITH NT HEALTH STAFF, CLIENTS/PATIENTS, SITES AND/OR DATA**  *All research studies conducted with NT Health staff, clients/patients, sites and/or data require organisational authorisation. The* ***NT Health Research Governance Office (RGO)*** *will facilitate this process, ensuring that the principles, requirements and standards for organisational governance of research are implemented.*  *Researchers must include evidence of endorsement by the local Regional Health Service authorising delegates (i.e. Unit Head, Co-Director or Director of Research, General Manager or )****prior to submission to the NT Health RGO****by completing the relevant endorsements sections below or by submitting email endorsement when lodging this form via*[***nthealth.rgo@nt.gov.au***](mailto:nthealth.rgo@nt.gov.au)*. Please ensure that email endorsements include the project title. If unsure of the appropriate authorising delegate(s), please contact NT Health RGO for advice.*  *The completed form should be submitted electronically to the NT Health Research Governance Office (RGO) via* [***nthealth.rgo@nt.gov.au***](mailto:nthealth.rgo@nt.gov.au)*for NT Health Organisational Approval. The RGO will forward this form to the ethics office for expedited review.* | | | |
|  | Name | Signature | Date |
| PI’s Supervisor |  |  |  |
| Site Supervisor for students (if applicable) |  |  |  |
| Unit Head |  |  |  |
| Regional Health Service Authorising Delegate |  |  |  |

\* Researchers should be guided in their activities by the *National Statement on Ethical Conduct in Human Research 2007 (updated 2018)*.

***\*NT Health RGO Office only***

**NT Health Organisational Authorisation**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Name | Signature | Date |
| Executive Director of Research |  |  |  |