**Central Australian Human Research Ethics Committee**

**This application should be completed in terminology readily understood by an informed layperson. For example, the first time an acronym is used in the application the words must be written out in full, with the acronym placed in parentheses immediately after.**

**The application should be complete, with all relevant documentation attached.**

**(See checklist at the end of the application form).**

**Applicants should have read, and be familiar with, the following documentation and ensure that the application is consistent with:**

* Australian Government *Australian Code for the Responsible Conduct of Research*, 2007
* NHMRC *National Statement on Ethical Conduct in Human Research,* 2007
* NHMRC *Values and Ethics : Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*, 2003
* *The Commonwealth Privacy Act, 1988.* NHMRC has issued Guidelines Under Sections 95 and 95A of the Privacy Act 1988
* *The Northern Territory Information Act,* 2002

**SUBMISSIONS:**

**Please check the CAHREC website for monthly submission deadlines.**

**These deadlines are final.**

The following documents must be received by the deadline for an application to be included in the Ethics Committee meeting:

* **1** ***stapled, single-sided, signed original***, including all attachments (with original or digital signatures)
* **20** ***stapled, double-sided, hard copie*s** of the signed original, including all attachments
* **1** ***electronic copy*** of the signed original, including all attachments:

**please email these through as one document, not as multiple attachments**

**PLEASE DO NOT INCLUDE THIS EXPLANATORY SHEET IN THE PROJECT SUBMISSION.**

Applications for **clinical trials or complex research programs** should include **5** copies of the **detailed scientific protocol** in addition to the above.

**If the Principal Investigator will not be contactable** on his/her normal phone number (as listed in the application) when the Central Australian Human Research Ethics Committee convenes, **please supply additional details on how he/she may be contacted** during the meeting times, as listed on our website.

Should you have any queries regarding the Central Australian Human Research Ethics Committee, or its application form, please contact the CAHREC Secretariat on **08 8951 4700** or email cahrec@flinders.edu.au

**Central Australian Human Research Ethics Committee**

**Application Form**

|  |
| --- |
| **Principal Investigator’s name (including title):**Dr Gargi Kanabar |
| **Project Title:**qSOFA in a remote and mainly Indigenous Australian population; does it work and can it improve outcomes? |
| **Simplified Project Title** (Optional)**:** |
| **Organisation accepting responsibility for the project:**Central Australian Health Service |

**Additional contact for email correspondence, if applicable:**

**Office Use Only**

Application ID :

Date Received :

**Name (including title):**

Richard Johnson

Director of Retrieval Service and Emergency consultant Alice Springs Hospital

|  |  |  |  |
| --- | --- | --- | --- |
| **Phone:** | 89517657 | **Fax:** |  |
| **Email :** | Richard.johnson@nt.gov.au |

**Part A. THE INVESTIGATORS**

|  |  |
| --- | --- |
| **Principal Investigator’s Name**This is the person with overall responsibility for the conduct of the project and reporting against it. If this is a postgraduate student or medical trainee, the supervisor/s must also be listed as investigators. | Dr Gargi Kanabar |
| **Qualifications** |  |
| **Organisational Affiliation** |  |
| **Position** |  |
| **Postal Address** |  |
| **Phone** |  | **Fax** |  |
| **Email**  |  |
| **Summary of expertise relevant to this research****NS 4.8.7 NS 4.8.15** |   |
| **Please declare any competing interests** |  |

|  |  |
| --- | --- |
| **2nd Investigator’s Name** | Dr Richard Johnson |
| **Qualifications** | MBBS, MRCS, DTM&H, FCEM, FACEM |
| **Organisational Affiliation** | Central Australian Health Network |
| **Position** | Director of Retrieval Medicine, Consultant in Emergency Medicine |
| **Postal Address** |  |
| **Phone** | 08 89517657 | **Fax** |  |
| **Email**  | Richard.johnson@nt.gov.au |
| **Summary of expertise relevant to this research****NS 4.8.7 NS 4.8.15** | Dr Johnson is a specialist in Retrieval and Emergency medicine who has been employed as the Director of Retrieval at Central Australian Health Services since January 2012. He has previous experience as a consultant in Emergency Medicine in Newcastle-upon-Tyne, UK. He obtained Fellowship of the UK College of Emergency Medicine in 2010 and the Australasian College for Emergency Medicine in 2012.Current areas of responsibility are as Director of Retrieval providing critical care retrieval services to the whole of Central Australia as well as responsibility for recruitment, education, training and rostering.Previous research experience has been with the University of Newcastle-upon-Tyne, UK facility of Surgery MD project with several publications.He currently holds an Honorary Academic Fellow post with Baker IDI and is involved in several ongoing research projects. |
| **Please declare any competing interests** | **none** |

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| **3rd Investigator’s Name** | Dr Simon Walsh |
| **Qualifications** | MB BCh BAO, MRCS, FACEM |
| **Organisational Affiliation** | Central Australian Health Network |
| **Position** | Consultant in Emergency Medicine and Retrieval Medicine |
| **Postal Address** |  |
| **Phone** | 08 89517657 | **Fax** |  |
| **Email**  | Simon.Walsh@nt.gov.au |
| **Summary of expertise relevant to this research****NS 4.8.7 NS 4.8.15** | Dr Walsh is a specialist in Retrieval and Emergency Medicine. He has previously worked as a consultant in St Vincent’s Emergency Department, Melbourne. He obtained his Fellowship with the Australian College for Emergency Medicine in 2015.Current areas of responsibility are in Retrieval and Emergency medicine, providing critical care retrieval services to the whole of Central Australia as well as responsibility for education, training and rostering.He is also a co-Director of Emergency Medical Training in Alice Springs Hospital (ASH). |
| **Please declare any competing interests** | **none** |

**Copy and Paste tables to include more Investigators as necessary**

**Student Investigators**

|  |  |
| --- | --- |
| **1st Student’s Name** |  |
| **Qualifications** |  |
| **Degree Being Undertaken** |  |
| **Enrolling University** |  |
| **Primary Supervisor** |  |
| **Student’s Postal Address** |  |
| **Phone** |  | **Fax** |  |
| **Email** |  |
| **Summary of expertise relevant to this research****NS 4.8.7 NS 4.8.15** |  |
| **Please declare any competing interests** |  |

**Copy and Paste tables to include more Students as necessary**

**Describe what training students and co-researchers will receive N/A [ ]**

 **⏵Go to Part B**

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**Part B. THE PROJECT**

|  |  |
| --- | --- |
| **Title:** |  |

**1. Type of project:**

 (**Formatting Tip:** Tick all relevant boxes by double-clicking on the box and marking ‘Default Value’ as ‘Checked’)

**[ ]  Funded research** (complete Q32)**[x]  Staff research**

**[x]  Un-funded research [ ]  Student – postgraduate research**

**[ ]  Audit** **[ ]  Student – postgraduate coursework**

**[x]  Clinical trial notification** **[ ]  Clinical trial exemption**

 **scheme** (Attach 5 copies of protocol  **scheme** (Attach 5 copies of protocol

evidence of insurance, and trial and evidence of insurance, and trial

 registration number) registration number)

**2. Is this project a continuation of a current or previous project with ethics approval?** **[ ]  Yes** **[x]  No**

 **If YES, please provide CAHREC identification number:**

**3. Has this project been submitted to any other ethics committees?**

 **[ ]  Yes [x]  No**

 **⏷**

**If YES, please provide the following details :**

|  |  |  |  |
| --- | --- | --- | --- |
| **Ethics Committee**(incl. Human, Animal and Biosafety Committees) | **Status** (To be Submitted, Submitted, Approved,Not Approved) | **Date** | **Copy of Ethics Approval Attached?** |
|  |  |  |  |
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**4. Proposed commencement date of project: April 2017**

**5. Proposed completion date of project: December 2017**

**6. Summary of the project:**

 In the box below, describe the project in 100 words or less.

 (**Formatting Tips:** To tab within a box, hold down the ‘Ctrl’ key when you press the ‘Tab’ key.

 All boxes automatically expand in length)

|  |
| --- |
| In order to validate the sepsis-3 quick Sequential Organ Dysfunction Assessment (qSOFA) score in a remote ED population and setting, it will be compared retrospectively by case note review against the Systemic Inflammatory Response Syndrome (SIRS), Remote Early Warning Score (REWS) and Medical Emergency Warning Score (MEWS) for rates of Intensive Care Unit/High Dependency Unit (ICU/HDU) admission and in-hospital mortality.A prospective introduction of the qSOFA score with and without point of care lactate as an early warning tool at the first point of contact with ASH ED triage and its use as an alert for early senior medical staff involvement, will attempt identify the most efficient way to shorten the time to treatment of patients with severe infections.  |

**7. Background to the project:**

 Briefly describe the history of the topic you intend to address.

 A formal literature review should have been conducted and be evident in your application.

|  |
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| Sepsis is one the leading causes of mortality in hospitalised patients.1,2 However, identifying patients with sepsis can be difficult with variable clinical presentations and no gold standard test for serious infection. Sepsis research has however resulted in overall reduction in mortality globally.3Sepsis-3 has recently redefined sepsis as life-threatening organ dysfunction caused by a dysregulated host response to infection.4The Systemic Inflammatory Response Syndromes (SIRS) criteria, consisting of temperature, white cell count (WCC), heart rate and respiratory rate, has previously been recommended by the surviving sepsis campaign to identify patients with significant organ dysfunction secondary to infection.5,6The SIRS criteria, however, have been shown to have some limitations suggesting that a new model was required. It has been found that 50% of general ward patients and 90% of intensive care unit patients (ICU) will meet SIRS criteria at some point during their stay, many of which did not incur adverse outcomes.7 SIRS, therefore, may represent an appropriate host response to infection but not necessarily indicate organ dysfunction. It has since also been seen that 1 in 8 critically unwell patients, admitted to the ICU, did not meet SIRS criteria.8 It was also recognized that SIRS, as well as more recently recommended criteria used to recognize sepsis including sequential organ function assessment (SOFA) and Logistic Organ Dysfunction System (LODS), which aim to highlight organ dysfunction, have limitations in the ED given several laboratory and clinical measurements are required.9,10As a result, Sepsis-3 has discarded SIRS and a new construct ‘qSOFA’ has been introduced. Singer et al, as part of the Sepsis-3 investigation, have recommended the use of the qSOFA criteria in patients outside the ICU where infection is suspected. The qSOFA score measures respiratory rate (≥22 breaths per minute), altered mental state and systolic blood pressure (<100mmHg). Each criterion, if positive, is given one point. A score greater than 1 indicates the possibility of sepsis. The qSOFA criteria was shown to have a predictive validity outside the ICU that was greater than SIRS and SOFA and was shown to identify patients who were likely to have a prolonged ICU stay or die in hospital.9Validation of qSOFA for Sepsis-3 was limited in that only a retrospective study was carried out in a single population group. It has been suggested by Seymour et al, as part of the Sepsis-3 study, that prospective validation in low to middle income countries would aid direction. Recent prospective study has suggested that the qSOFA score is highly sensitive but not specific which may limit its utility as a bedside screen.11 In addition, serum lactate, which can be easily measured on arrival by taking a venous blood gas, has not been included in the score. It is currently unclear as to whether or not the addition of a lactate measurement would be useful. It was shown that patients with a serum lactate > 2mmol/L and a qSOFA score of 1 had a higher mortality compared to those with a lactate < 2mmol/L. The rate of mortality was similar to those with a qSOFA score of 2.4Alice Springs hospital (ASH) is the only hospital serving an area more than 500 000km2, populated by about 15,000 Indigenous and 25,000 non-Indigenous Australians. More than 70% of all medical inpatients are Indigenous with 60% of deaths among Indigenous patients associated with infection, predominantly bacterial in source. This is comparable to those from resource-poor regions with the proportion of infection related adult mortality in Alice Springs being similar to those in African hospitals before the HIV pandemic.12,13Reducing the time to antibiotics has consistently been shown to improve survival in sepsis and severe sepsis14,15 and processes to identify sepsis early and alert systems to the potential for sepsis have been shown to reduce the time to antibiotics.15,16 This project would look at understanding and developing the most efficient way of early identification of patients at risk of sepsis and severe sepsis and it is suggested that by doing so we could reduce the time to antibiotics and therefore mortality.It would therefore be prudent to identify a method to recognise sepsis and organ dysfunction early in the central Australian population with the qSOFA score potentially being an easy tool to use as patients present to the ED. We therefore would like to assess the validity of qSOFA in this population. References 1. Lagu T, R. M. (2012). Hospitilizations, costs and outcomes of sevre sepsis in the United States 2003 to 2007. *Crit Care Med* *, 40*, 754-761.2. Liu V, E. G. (2014). Hospital deaths in patients with sepsis from 2 independent cohorts. *JAMA* *, 312*, 90-92.3. Levy MM, R. A. (2015). Suviving Sepsis Campaign: association between performance metrics and outcomes in a 7.5-year study. *Crit Care Med , 43* (1), 3-13.4. Singer M, D. C.-H. (2016). The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3). *JAMA* *, 315* (8), 801-810.5. Dellinger PR, L. M. (2013). Surviving Sepsis Campaign: International Guideleines for Management of Severe Sepsis and Septic Shock: 2012. *Crit Care Med* *, 41* (2), 580-620.6. Levy MM, F. M. (2003). 2001 SCCM/ESICM/ACCP/ATS/SIS International Sepsis Definitions Conference . *Intensive Care Med* *, 29* (4), 530-538.7. Vincent JL. (1997). Dear SIRS, I'm sorry to say that I don't like you. *Crit Care Med* *, 25* (2), 372-374. 8. Kaukonen KM, B. M. (2015). Systemic Inflammatory Response Syndrome Criteria in Defining Severe Sepsis . *NEJM* *, 372* (17), 1629-1638.9. Seymour CW, L. V. (2016). Assessment of Clinical Criteria for Sepsis For the Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3). *JAMA* *, 315* (8), 762-774.10. April MD, A. J. (2016). Sepsis Clinical Criteria in Emergency Department Patients Admitted to an Intensive Care Unit: An external validation study of Quick Sequential Organ Failure Assessment . *J Emer Med* , 1-10.11. Williams JM, G. J. (2016). SIRS, qSOFA and organ dysfunction: insights from a prospective database of emergency department patients with infection. *Chest* .12. Einsiedel LJ, F. L. (2008). Racial disparities in infection-related mortality at Alice Springs Hospital, Central Australia, 2000-2005. *MJA* *, 188* (10), 568-571.13. Petit PLC, v. G. (1995). Analysis of hospital records in four African countries, 1975-1990 with emphasis on infectious diseases. *J Trop Med Hyg* *, 98*, 217-227.14. Ferrer R. 2014. Empiric antibiotic treatment reduces mortality in severe sepsis and septic shock from the first hour: results from a guideline-based performance improvement program Aug;42(8):1749-55.15. de Groot, B. (2015). The association between time to antibiotics and relevant clinical outcomes in emergency department patients with various stages of sepsis: a prospective multi-center study16. McGregor C. (2014). Improving time to antibiotics and implementing the “sepsis6”,. BMJ Qual Improv Report 2014;2: doi:10.1136/bmjquality.u202548.w14443 |

**8. Aims of the project:**

 Briefly describe your primary research question and what outcomes you hope this project will achieve.

|  |
| --- |
| The SEPSIS-3 group suggest the use of qSOFA in early screening for severe infections but this score has only been validated in large urban populations with a mainly Caucasian demographic. The aim of the study will be to assess the score’s validity in the population presenting to ASH ED and whether it can be used to improve patient and system outcomes in terms of early identification of patients with severe infection by:Primary outcome:To measure whether the use of qSOFA at triage in ASH ED improves the time to recognition and treatment in patients with severe infections.This will evaluate the role of a sepsis alert tool and ‘sepsis pager’ in ASH ED aiming to reduce ICU admissions.To assess whether the addition of a point of care lactate to qSOFA at triage in ASH ED improves the time to recognition and treatment in patients with severe infections.Point of care lactate represents an easy, cheap and accessible measure of organ dysfunction that is utilised at some point on almost all patients with infections in ASH ED. By changing the order of working and using a ‘sepsis pager’ to apply this very early in the patients’ hospital journey the study will assess whether this improves identification and shortens time to treatment and reduces ICU admissions.Secondary outcomes:To measure sensitivity and specificity of qSOFA in patients with severe infections at risk of requiring ICU level treatment and in-hospital mortality in a timely manner in a remote ED setting with a large Indigenous Australian population.This will inform the service whether to replace current early warning tools with qSOFA in line with SEPSIS-3 guidelines.The ability to predict a poor outcome does little for patients and systems without the ability to reduce the impact of the risk. The ‘sepsis team’ and point of care lactate aim to provide earlier identification and treatment to improve outcomes, and this study aims to evaluate the change. |
|  |
|  |

**9. Justification:**

Outline the justification of the proposal.

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| --- |
| Despite worldwide improvement in the survival of patients with sepsis and severe sepsis it continues to have a high mortality and contributes significantly to the workload of ASH ED, in-patient teams and ICU. An efficient way of identifying these patients and shortening the time to treatment would have individual, population and system benefits. |

**10. Participants:**

 Please read the relevant sections of the *National Statement, Commonwealth Privacy Acts* and *Northern Territory Information Act* to assist you in completing this question. These documents are available on the **Ethics** page of the **Menzies School of Health Research** website: <http://www.menzies.edu.au>)

 (**Formatting Tip :** Tick *all* relevant boxes by double-clicking on the box and marking ‘Default Value’ as ‘Checked’)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Specific Participant Groups** | **Targeted** | **Probable** **Incidental** | **Excluded** | **Relevant Section of National Statement/ Privacy Act** |
| [ ]  | Participation of, or impact upon, women who are pregnant and the human foetus | [ ]  | [ ]  | [x]  | 4.1 (NS) |
| [ ]  | Participation of, or impact upon, children and young people (see ***Working With Children Clearance section below***) | [ ]  | [ ]  | [x]  | 4.2 (NS)NT Care & Protection of Children Act  |
| [ ]  | Participation of, or impact upon, people in dependent or unequal relationships (*e.g.* patients and health care professionals; students and teachers; employees and supervisors/employers; prisoners and prison wardens; government authorities and refugees; service providers and recipients of those services) | [ ]  | [ ]  | [ ]  | 4.3 (NS) |
| [ ]  | Participation of, or impact upon, persons highly dependent on medical care who may be unable to give consent | [ ]  | [x]  | [ ]  | 4.4 (NS) |
| [ ]  | Participation of, or impact upon, people with a cognitive impairment, an intellectual disability, or a mental illness | [ ]  | [x]  | [ ]  | 4.5 (NS) |
| [ ]  | Participation of, or impact upon, people who may be involved in illegal activities | [ ]  | [ ]  | [x]  | 4.6 (NS) |
| [ ]  | Participation of, or impact upon, Aboriginal and Torres Strait Islander Peoples | [ ]  | [x]  | [ ]  | 4.7 (NS) |
| [ ]  | Participation of, or impact upon, people in other countries | [ ]  | [ ]  | [x]  | 4.8 (NS) |

 **Will researchers potentially have contact with Children? [ ]  Yes [x]  No**

 If yes, please provide:

|  |  |  |
| --- | --- | --- |
| Researcher Name | Ochre Card Number | Clearance Expiry Date |
|  |  |  |
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Please attach copies of Ochre Cards and Clearance Notices with other documentation

**11. Participant/ subject level of involvement and selection criteria:**

Briefly describe on what basis participants/subjects will be included in, or excluded from, the project, the recruitment process that will be used, and the participants/subjects level of involvement.

|  |
| --- |
|  All patients presenting to Alice Springs Hospital Emergency Department with clinical symptoms suggestive of an infective cause as determined by the triage nurse who have 2 or more criteria as defined by qSOFA will be included. Patients under the age of 18 and pregnant women will be excluded. |

**12. Design & methodology:**

Briefly outline the methods you propose using to achieve the aims of the project including data analysis methodology.

**Attach copies of questionnaires or other instruments to be used**.

**All Clinical Trials must be registered with a publically available register**

**(**[**www.clincaltrials.gov**](http://www.clincaltrials.gov) **or** [**www.ANZCTR.org.au**](http://www.ANZCTR.org.au)**) Please provide registration number.**

|  |
| --- |
|  Study DesignThis study contains both a retrospective review of case notes and a prospective block randomised trial. It is designed to assess the validity of the qSOFA score in the identification of adult, non-pregnant patients with severe infections at risk of needing ICU/HDU admission or death, and to evaluate an early action system triggered by that warning. Subjects and materials1. Retrospective case note review

In order to ascertain the validity of the qSOFA score in adult, non-pregnant patients presenting to the ASH ED, case notes of this patient group who presented to ED with symptoms suggestive of infections will be reviewed.Physiological measurements (observations) taken at triage and the first set of measurements taken in the main ED department will be used to calculate a qSOFA score. As per the original qSOFA primary endpoints, rates of ICU/HDU admission and in-hospital mortality will be used to calculate sensitivity and specificity.The same data will then be used to calculate sensitivity and specificity for the currently used tools FlightLights (pre-hospital) and MEWS (in-hospital)System performance data will also be collected for comparison with prospective study data1. Prospective block randomised trial

All patients presenting to the ASH ED triage system by self-referral or by ambulance service or RFDS with symptoms or signs suggestive of infection (as assessed by the triage nurse) will have a qSOFA score calculated.If any patient with a triage suggestive of infection and a qSOFA score of 1 or more then the patient will be brought to the attention of the ‘sepsis team’ which will consist of a member of junior medical staff and a registrar (midnight to 0730hrs) or consultant for group 2 and registrar/consultant notification only for group 1. For group 2 patients the junior medical staff or nurse at triage will perform a point of care lactate within 10 minutes of triage.Block randomisation will be by week on, week off. This has been chosen as a pragmatic solution to allow for variations in ED department rostering, triage nurse workload, clinical decision making intervariability and to reduce cross-over between arms.Data collected will include, admission to ICU/HDU, in-hospital mortality but also parameters of system performance to include time to consultant review, time to taking of microbiological specimens for culture, administration of antibiotics and specialist referral, including ICU.It is important to comment that no actual physical changes to what tests and treatment patients will receive should result from this randomisation, the sole change is the timing of a blood test from late in the process of assessment and ‘work-up’ to as close to the point of contact as possible.The data will then be analysed using non-parametric statistical methodology to identify a difference between the two groups in time to treatment and referral patterns.A mid-recruitment statistical analysis and a review of protocol will be performed to ensure that there is not a large or statistically significant difference in outcomes that would necessitate early closure. |

**13. Sample size:**

|  |  |
| --- | --- |
| TOTAL SAMPLE SIZE | 1600 |
| PARTICIPANTS | 800 |
| RECORDS | 800 |

 Briefly outline and justify the sample size to be used in research.

|  |
| --- |
| Retrospective phase; 800 case note review suggests that at 4 patients per day this will be between 6 and 7 months attendences in ED with symptoms clinically suspicious of infection and abnormal physiologyProspective phase two; power calculations to detect a reduction in time to antibiotics to median below 60 minutes from the current level of >120minutes we require 63 patients per groupProspective phase three; with an assumed 40% positive rate of point of care lactate in the population presenting to Alice Springs emergency department and aiming for a clinical significance of 10% increase in early administration of antibiotics we require 393 patients in each group |

**14. Collection & use of data:**

 Please read the relevant sections of the *National Statement, Commonwealth Privacy Acts* and *Northern Territory Information Act* to assist you in completing this question. These documents are available on the **Ethics** page of the **Menzies School of Health Research** website: <http://www.menzies.edu.au>)

 (**Formatting Tip:** Tick *all* relevant boxes by double-clicking on the box and marking ‘Default Value’ as ‘Checked’)

|  |  |  |
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|  | **Collection and Use of Data** |  |
| [ ]  | Collection and/or use of *non-identifiable data* – where individual identifiers have never existed or been permanently removed |  |
| [ ]  | Collection and use of *re-identifiable data* with the individual’s consent – where the identifiers have been removed and replaced with a code, but it remains possible to re-identify a specific individual (*eg*. through linkage of data sets) |  |
| [ ]  | Collection and use of *individually identifiable data* with the individual’s consent - where individual participants may be identified |  |
| [ ]  | Collection of *identifiable data* from records held by a Commonwealth government agency without consent of individuals | S95: NPPs (PA) |
| [x]  | Collection of *identifiable data* from records held by a State or local government agency without consent of individuals | NT Info Act |
| [ ]  | Collection of *identifiable data* from records held by a private sector agency without consent of individuals | S95A: IPPs (PA) |
| [ ]  | Use of data previously gathered for another research project – where consent was provided for future use | 2.2.14 (NS) |
| [ ]  | Use of data previously gathered for another research project – where consent was *not* provided for future use | 2.2.18 (NS) |

**15. Research methodology:**

 Please read the relevant sections of the *National Statement* to assist you in completing this question.

 (**Formatting Tip:** Tick *all* relevant boxes by double-clicking on the box and marking ‘Default Value’ as ‘Checked’.)

|  |  |  |
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|  | **Research Methods** |  |
| [x]  | Research involving pre-existing data sets |  |
| [ ]  | Qualitative research – disciplined inquiry that examines people’s lives, experiences and behaviours and the stories and meanings ascribed to them – through interviews, focus groups, observation, archival, on-line, and/or action research | 3.1 (NS) |
| [ ]  | Conducting non-invasive physical experiments or examinations |  |
| [ ]  | Conducting trials – trialling new interventions and therapies, including clinical and non-clinical trials, and innovations | 3.3 (NS) |
| [ ]  | Research involving human tissue or biological samples | 3.4 (NS) |
| [ ]  | Research involving human genetics – studying the structure, location, function, expression, interaction, abnormalities and effects of the genes | 3.5 (NS) |
| [ ]  | Research involving human stem cells | 3.6 (NS) |
| [ ]  | Research involving exposure to ionising radiation (\*Attach certificate from ionising radiation expert) |  |

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|  | **Other Considerations** |  |
| [ ]  | Use of material or procedures of potential danger to the environment |  |
| [ ]  | Collecting archaeological data including or impacting upon human remains |  |

**16. How will the identity and privacy of participants be protected?**

If identifying information is to be made public, justify the public identification of individual participants or communities.

|  |
| --- |
| Data sheets will not record easily identifying information (patient’s name or hospital record number), although some demographic data will be recorded as noted above (Date of Birth, gender, ethnicity) but rather will have a separate record number. A key linking the audit record number and hospital record number will be kept separately. Publications or presentations will present group data only; specific individual or case data sets will not be presented.  |

**17. Outline procedures to be followed in the event of a participant withdrawing consent or dying:**

|  |
| --- |
| 1. Retrospective case note review; waiver of consent is sought for this component of the study.
2. Prospective trial

If the patient wishes to withdraw consent, then they will, without prejudice, or change to clinical management, be removed from the data collection and recording of the studyDeath is one of the primary outcome measures so that will be recorded as such. |

**18. Will payments be made to participants? [ ]  Yes [x]  No**

 **⏷ ⏵Go to Q19**

**If YES**, please provide information regarding the nature of, and reasons for, these payments e.g. reimbursement of costs, incentives to participate, etc. Explain why it will not form an inducement to participate.

|  |
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|  |

**19. English as a second language:**

Briefly describe how you will ensure that participants whose first language is not English understand the project’s aims and what they may be agreeing to.

|  |
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| All attempts will be made to ensure that the patient understands the aims and data collection and privacy involved. If there are concerns, then input, advice and interpretation from the Aboriginal Liaison service will be requested at the earliest opportunity.Due to the fact that the study will not change any clinician’s decision making and any actual investigation or treatment that the patient receives, it is not deemed necessary for the consent to be gained for triage or lactate assessment but for the data collection and recording, therefore consent may be obtained later, when ALOs are available. |

**20. How will your proposed methodology ensure respect for the cultural, social and religious beliefs and customs, or cultural heritage of participants?**

Exclusion: **For research involving Indigenous Australians**, please complete Section D of the application form and enter “*Indigenous Australians – See Section D*” in this box

|  |
| --- |
| It is recognised that the majority of records audited will be of individuals who identify as Indigenous Australians and that it may be necessary to review files of persons who are now deceased. As outlined above, images and names of individuals will not be recorded.  |

**21. Consent Procedures:**

 Please read the relevant sections of the *National Statement, Commonwealth Privacy Acts* and *Northern Territory Information Act* to assist you in completing this question.

 (**Formatting Tip:** Tick *all* relevant boxes by double-clicking on the box and marking ‘Default Value’ as ‘Checked’)

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Consent Procedures** | **Any Relevant Documents Attached** |  |
| [x]  | Informed consent – documented consent of individual | [ ]  | 2.2 & 5.2.16 (NS) |
| [ ]  | Informed consent – documented assent of guardian | [ ]  | 2.2.12 & 5.2.16 (NS) |
| [ ]  | Informed consent – documented support of community, institutions or other properly interested parties representing collective interests | [ ]  | 2.2.13 & 4.7.2 (NS) |
| [ ]  | Limited disclosure – not involving active concealment or planned deception | [ ]  | 2.3.1 (NS) |
| [ ]  | Limited disclosure – involving active concealment or explicit deception | [ ]  | 2.3.2 (NS) |
| [x]  | Waiver of consent – for research using personal information | [ ]  | 2.3.5 (NS) |
| [ ]  | Consent not required – for research using pre-existing non-identifiable data  |  |  |
| [ ]  | Other Explanation: | [ ]  |  |

**22. Will written informed consent be sought? [x]  Yes [ ]  No**

 **⏷ ⏵Go to Q23**

**If YES**, please attach copies of the proposed Consent Form and Information Sheet.

**The Consent Form** should allow for the participant to agree to: each proposed intervention, the proposed storage or destruction of any biological samples, being videoed or audio-taped, the proposed level of confidentiality and any dissemination of results.

It is important that the consent form states in **bold** ‘**This means you can say no’.**

**The Information Sheet** should be given to the participant to keep, and should contain contact details for the researcher/s in case of an emergency and the HREC Secretariat in case of concerns or complaints. It should state in **bold**: ‘**This is for you to keep’.**

**Both** should clearly provide information allowing for the participant to withdraw from the project or not participate at all.

**23. Will you be accessing personal information *without* consent?**

 **[x]  Yes [ ]  No**

 **⏷ ⏵Go to Q24**

 **(a) If YES, from which organisation/s do you intend to collect information?**

Please note that receipt of HREC approval does not place any obligation on the proposed organisation/s to provide the requested information.

**Evidence of support from the information provider should be attached to this application.**

|  |  |  |
| --- | --- | --- |
| **Organisation** | **Contact Person** | **Phone No.** |
| Central Australian Health Service | Samuel Goodwin |  |
|  |  |  |

**(b) Provide details about the information you intend to collect:**

Detail what sort of information you intend to gather from the listed Organisation/s. ***You must state*** whether the Information will be gained in an **Individually** **Identifiable, Re-Identifiable, or Non-Identifiable** format.

**If the information is Individually Identifiable or Re-Identifiable, justify the need for the identifying information – remember that public interest must outweigh an individual’s right to privacy**.

|  |
| --- |
| The information collected about individuals is listed on the attached Data Collection Sheet. Individually identifiable data will, where possible, not be recorded (although it is recognised that, given the small size of many communities in Central Australia, it may be possible to identify an individual through date of birth and gender). It is important that data be re-identifiable via a key, in order to be able to check the accuracy of databases, and to identify repeat patients (who may have been transported more than once).  |

**(c) Why will individual consent not be sought?**

 If you are gathering Individually Identifiable or Re-Identifiable information, justify your reasons for not seeking individual consent.

|  |
| --- |
| 1. Retrospective case note review

It would be unfeasible to individually contact all the participants to obtain consent. This is because of the number of patients involved in the retrospective component and the remote nature of the communities where a large cohort of the individuals live (meaning that it is not practical to visit all of them), the lack of ability to reliably contact them by other means (most communities do not have cell phone coverage and many houses lack phones).  |

**24. Proposed storage of, and access to, data:**

Provide details as to:

A) how and where the data will be stored and who will have access to it *during* the project

B) how and where the data will be stored, for how long, and how it will be disposed of *after* the project

C) detail any agreements with 3rd parties to be given access to the data

*Please note: The Australian Code for the Responsible Conduct of Research* provides guidance on Management of Research Data and Primary Materials (Section 2), including retention, storage, ownership, security and confidentiality.

|  |
| --- |
| Hard copy data sheets will be stored in a locked filing cabinet in the office of the 2nd investigator (Dr Johnson). During the audit and data analysis period an electronic database will be kept in the shared drive personal folder of the principal investigator, and a copy in the folder of the second investigator. This will be accessible only to the investigators. Following the audit completion, the individual data sheets will be destroyed. The database will be stored on the secure Central Australian Health Service shared drive.  |

**25. Participant feedback, dissemination of results, and publication:**

Briefly explain how you intend to inform the wider public (including any publications from the research) as well as provide feedback to participants and communities of the project’s outcomes, and their own results if applicable. If you ***do not*** intend to provide participants with feedback, state why this is considered unnecessary.

|  |
| --- |
| The results will be disseminated internally through poster and presentation at ASH grand rounds and education centre.The results will be shared with remote health, RFDS and St John’s Ambulance to assist in their pre-alert systems for sick patients.It is the intention of the investigators to publish the data in regional and national scientific meetings within the Emergency medicine community and publish in scientific journals. |

**26. Anticipated outcomes:**

Detail the anticipated outcomes from the project and how they will contribute new knowledge to the field as well as any potential applications of the findings.

Justify the risks in terms of the likely benefit gained.

|  |
| --- |
| Primary outcome* To provide evidence for or against the use of point of care lactate testing at triage.
* To introduce a system change enabling a shortening of the time to treatment of patients with sepsis and severe sepsis in the expectation that, on a population basis, this will improve outcomes in terms of reduced admission to ICU and reduced mortality.

Secondary outcomes* Validation of qSOFA in a non-tertiary centre population to support or refute its ongoing use.
 |

**27. Intellectual property:**

If there is a possibility of commercial exploitation of the results, has agreement been reached with participants in relation to ownership of intellectual property? Describe any potential abuses or misapplications of the results of your project.

|  |
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| N/A |

**28. Timeline:**

Please provide a proposed timeline for the project from commencement to completion.

Note: The term “Completion” includes outputs such as feedback of findings, publication of the research, etc.

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| It is hoped that retrospective data collection will be completed by mid-May.It is hoped that recruitment of prospective patients will commence by May and be completed by December 2017.Preliminary data may be able to be presented by early 2018. Submission for publication is anticipated by late 2018.  |

**29. Risk management strategy:**

Describe the potential risks involved with the project and how you plan to manage these.

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| --- |
| It is not anticipated that this research will result in risk to individuals whose files are audited. As this does not involve any difference in actual treatment or investigative modality, it is not anticipated that any risk will be involved to any patient.Mid-recruitment analysis will be performed to ensure no one group is being statistically significantly disadvantaged. |

**30. Possible Investigator Conflicts of Interest:**

**(a) Do any potential ‘dependent or unequal relationship’ issues arise between any of the named investigators and the conduct of this research?** (e.g. relationships between researchers and participants that may compromise the voluntary nature of participants’ decisions).

 **Yes [ ]  No [x]**

 **⏷ ⏵Go to (b)**

(**If YES**, please provide details of the conflict of interest and mechanisms in place to address these issues)

|  |
| --- |
| All researchers are clinicians who may have been involved in care of the patients whose files will be audited, and may be involved in the clinical care of patients who are recruited prospectively but would not anticipate further contact with the patients during the course of the data analysis. |

**(b) Do any of the named investigators have access to personal or other sensitive information required for the conduct of this research as a condition of employment, rather than as a researcher?**

 **Yes [x]  No [ ]**

 **⏷ ⏵Go to(c)**

 (**If YES**, please provide details)

|  |
| --- |
| All researchers are clinicians in the employ of the Central Australian Health Service and, in the course of clinical duties, would have access to the files of patients involved in the audit if involved in those patients’ care or in the supervision of those providing such care. |

 **(c) Do any of the named investigators have any current or previous affiliation with, or financial involvement in, any organisation or entity with direct or indirect interests in the subject matter or materials of this research?**

 **Yes [ ]  No [x]**

 **⏷ ⏵Go to (d)**

 (**If YES**, please provide details regarding the nature of the affiliation/s and matters that may need consideration)

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|  |

**(d) Do any of the named investigators have any other potential conflict of interest issues not covered above?**

 **[ ]  Yes [x]  No**

 **⏷ ⏵Go to Q 31**

(**If YES**, please provide details regarding the nature of the conflict/s and matters that may need consideration)

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|  |

**31. Summary of ethical issues:**

Briefly summarise all the ethical issues related to this project. These should include at a minimum Benefit/Risk, Indigenous Involvement and Capacity Building and Generalisability.

**It is important to familiarise yourself with the National Statement on Ethical Conduct in Human Research (NHMRC) before attempting this summary.**

|  |
| --- |
| Retrospective case note review* As part of this, case notes and personal data will be accessed, but this will be de-identified and stored securely. No impact will accrue on the patient. If omissions or errors in management are identified during the case-note review, these will be notified to the treating team for rectification if clinically relevant and necessary.

Prospective randomised controlled trial* Consent will be sought from all patients following an explanation of the study and access to the patient information sheet.
* For patients with impaired conscious state, lactate and qSOFA will be taken and documented and consent sought when appropriate. Given that lactate is a normal part of the investigation of this patient group and all that is being altered is the timing, the investigators feel that this approach is reasonable and logical.
* At any point in time, if the patient wishes to withdraw, all data will be withdrawn from the study with change to the downstream treatment offered to the patient and no increased risk.
 |

**Part C. THE RESOURCES**

**32. Funding:**

(Name all sources of funding, sponsorship and interested parties)

**Has this project been submitted for funding?** **[ ]  Yes** **[x]  No ⏷ ⏵Go to Q33**

**If YES**

|  |  |
| --- | --- |
| **Name of Funding Body:** |  |
| **Title of Application:** |  |
| **Investigators Named on Application:** |  |
| **Duration of Support:** |  |
| **Status** (*ie*. Submitted, Funded)**:** |  |

**Basis of funding agreement:**

Provide details about any agreements regarding payment to researchers for enrolment of participants, power of veto over publication, etc.

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|  |

**33. Access to resources:**

Detail what resource support is required for the project to succeed e.g. obtaining data sets, accessing files, use of pathology services, health or community services staff resources and/or facilities etc, and whether you have already obtained the support of the necessary persons to access these resources.

**If applicable, attach any letters of support from resource provider/s-these letters should clearly state that the resource providers have considered the resource requirements from their institution and that they are prepared to meet them**.

|  |
| --- |
| CAHS Director of Medical and Clinical services, Sam Goodwin, has approved this study and file access. Hard-copy records will be obtained from ASH Medical Records via the ASH internal Audit process. IT hardware and software resources are available as NTG employees of the CAHS. |

**Part D. ABORIGINAL & TORRES STRAIT ISLANDER RESEARCH**

**34. Does this research require the participation of, or impact upon, Aboriginal & Torres Strait Islander people and/or communities?**

 **[x]  Yes [ ]  No**

 **⏷Go to (a) ⏷Go to (b)**

 **(a) If YES Describe how you have considered and addressed the following values:**

 **Reciprocity, Respect, Equality, Responsibility, Survival and Protection, Spirit and Integrity.**

 **(Note:** If you have responded to these specific criteria in a research funding application, you may attach the relevant page/s)

 **The NHMRC publication ‘*Values and Ethics: Guidelines for Ethical conduct in Aboriginal and Torres Strait Islander Health Research*’, which can be found on their website, provides information on all these values and their relevance to research.**

 **It is recommended that the researcher be familiar with this publication before completing this section.**

**(b) If NO, Advise *why* you believe this research does not involve, or impact upon, Aboriginal & Torres Strait Islander people**

Reciprocity - Mutual obligation;

 Benefit through the establishment or enhancement of capacities, opportunities or outcomes.

Respect - Acknowledgement of individual and collective contribution, interests and aspirations;

 Acknowledgement and affirmation of the rights to have different values, norms and aspirations.

Equality - Acknowledgement that all partners are equal, regardless that they may be different;

 The distribution of benefit;

 The value of collective memory and shared experience as a resource and inheritance.

Responsibility - To do no harm to individuals or communities, or to those things that they value;

 Establishment of processes to ensure researcher accountability to individuals and communities, particularly with respect to cultural and social dimensions of community life.

Survival & Protection - Protection against assimilation, integration and/or subjugation of values;

 Respect for social cohesion;

 Involvement that does not diminish the right to assertion or enjoyment of cultural distinctiveness.

Spirit & Integrity - Demonstration of credibility in intent and process;

 An approach that does not impede upon the richness and integrity of cultural inheritance.

Maximum 2 pages.

|  |
| --- |
| Although this research does not directly require the participation of, nor would be expected to directly impact Indigenous peoples/communities, it is expected that a significant proportion of patients recruited for the prospective study will identify as Indigenous, and a significant proportion of the patients for whom case notes are reviewed will be Indigenous.For this reason, we have chosen to address section D.1. ReciprocityData from this study will identify gaps in the global understanding and knowledge around the validity of sepsis scoring systems outside of large urban centres, specifically qSOFA. Outcomes from this study may contribute to improved efficiency of identification and system improvements for the benefit of patients, including, but not limited to those of Indigenous descent.2. RespectIt is important to acknowledge the difference in approach to medicine, models of disease, and the human life cycle. Additional information that may allow clinicians to better manage severe infections and sepsis, however, cannot be understated as there are potential advantages to future individual patients, as well as to the wider community.No judgement is implicit in any of the data gathered in this study.3. EqualityThe doctor-patient relationship has an inherent power imbalance; however, this study is designed to explore the validity of scorings systems, specifically the qSOFA in a population, both remote and inclusive of patients identifying as Indigenous Australians. It is expected that the results of this study will better inform clinicians allowing an improved level of care to be safely delivered to the local population.At the core of this study is an interest in mitigating the health effects of disadvantaged groups. Although it is anticipated that the vast majority of patients recruited to the retrospective component of this study will identify as Indigenous, this merely reflects the disease burden in the population serviced by the Alice Springs Hospital. This culturally neutral study attempts to provide further information about the implications of morbid obesity.4. ResponsibilityThis study collates and summarises data already used for usual clinical purposes. It does not include data that identifies, or describes specific individuals or communities. No additional burden is imposed on patients in undertaking this study. No additional tests or additional procedures will be carried out on patients as a result of participation in this study.5. Survival and ProtectionIt is not expected that either carrying out this project, nor the results will have any impact on social cohesion. The cultural distinctiveness of the Central Australian population will not be diminished in any way by this project.6. Spirit and IntegrityThe clearest demonstration of intent is that of increasing healthy life expectancy. By identifying a gap in the knowledge base around the early identification of severe infections, we may allow earlier return to health and a reduction in the complications of ICU.It is not thought that the study design or research methodology could in any way impede on the rich cultural inheritance that exists.References1 Trudgen, R. Why Warriors Lie Down and Die. Aboriginal Studies Press, 1991 |

**35. Community support:**

If you intend undertaking research in a community setting, identify the community/ies, outline whether discussions have been held with appropriate community representatives or community organisations and detail any processes in place for the conduct of the research project.

**Attach letters of support from the relevant community authorities-these letters should clearly state that community authorities are aware of the aims and methods of the proposed research**.

|  |
| --- |
| N/A |

**36. Ownership of traditional knowledge:**

 Who are the owners of any traditional knowledge? If relevant to your research, the consent form should include the clause, “*I understand that the ownership of Aboriginal knowledge and cultural heritage is retained by the informant and this will be acknowledged in research findings and in the dissemination of the research*”

|  |
| --- |
| No traditional knowledge will be used or impacted upon by this study. |

**Part E. SIGNATURES AND DECLARATIONS**

**TITLE OF PROJECT**:

**qSOFA in a remote and mainly Indigenous Australian population; does it work and can it improve outcomes**

* I certify that the information given is correct to the best of my knowledge
* I acknowledge that I must notify the Committee in advance of any ethically-relevant variation to the project
* I have read and agree to abide by the relevant parts of the NHMRC’s ***National Statement on Ethical Conduct in Research Involving Humans***

|  |
| --- |
| **Principal Investigator:** |
|   |   |   |
| Name | Signature | Date |

|  |
| --- |
| **2nd Investigator:** |
|   |   |   |
| Name | Signature | Date |

|  |
| --- |
| **3rd Investigator:** |
|   |   |   |
| Name | Signature | Date |

|  |
| --- |
| **4th Investigator:** |
|   |   |   |
| Name | Signature | Date |

|  |
| --- |
| **1st Student Investigator:** |
|   |   |   |
| Name | Signature | Date |
| **2nd Student Investigator:** |  |  |
|   |   |   |
| Name | Signature | Date |

If necessary, please copy and paste to include all researcher signatures. **TITLE OF PROJECT**:

**qSOFA in a remote and mainly Indigenous Australian population; does it work and can it improve outcomes**

* I certify that the information given is correct to the best of my knowledge
* I acknowledge that I must notify the Committee in advance of any ethically-relevant variation to the project
* I have read and agree to abide by the relevant parts of the **NHMRC’s *National Statement on Ethical Conduct in Research Involving Humans***

**Department Head/ Principal Investigator’s Supervisor:**

.................................... ......................................... ......................................................................

Title First Name Surname

....................................................................................

Position Title

........../........./......... .......................................................................

Date Signature

**Institutional Head**

I certify that

* I am aware of this project and its ethical issues and endorse its undertaking
* the Institution accepts responsibility for the ethical conduct*.* of the project as set out in the ***Australian Code for the Responsible Conduct of Research***
* I am aware of the resource requirements of this project and have determined they are available
* the researchers have the expertise and skills to undertake the research competently or will undergo the training outlined in this application to attain them

.................................... ......................................... ......................................................................

Title First Name Surname

.............................................................................................................................................................

Institution

....................................................................................

Position Title

........../........./......... .......................................................................

Date Signature

**CAHREC APPLICATION CHECKLIST**

Use this list to ensure the completeness of your application:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | **YES** | **NO** | **N/A** |
| **Other Human Research Ethics Committee Considerations** | Required? (*if so*, provide details under ‘The Project’ and attach copies of any responses already received) |  |  |  |
| **Instruments** (Questionnaires, etc) | Required? (*if so*, attach to each copy of the application) |  |  |  |
| **Consent Forms** | Required? (*if so*, attach to each copy of the application) |  |  |  |
|  | Written in Plain English |  |  |  |
|  |  “**This means you can say NO**” clearly displayed at the top of the consent form |  |  |  |
| **Information Statements** | Required? (*if so*, attach to each copy of the application) “**This is for you to keep**” clearly displayed at top of page |  |  |  |
|  | Written in Plain English |  |  |  |
|  | Researcher’s Contact included |  |  |  |
|  | Concerns or complaints contact (HREC Secretariat) included |  |  |  |
| **Resources** | Required? (*if so*, attach any letters of support to each copy of the application) |  |  |  |
|  | Funding available |  |  |  |
|  | Support Staff available |  |  |  |
|  | Agreement of other resource providers involved (*e.g*. Pathology Dept, etc.) |  |  |  |
|  | Letters of Support from Community Authorities/ relevant organisations |  |  |  |
| **Signatures** | All Investigators |  |  |  |
|  | Principal Investigator’s Supervisor  |  |  |  |
|  | Organisational Head including printed name and role in the Organisation.  |  |  |  |
| **Clinical Trials/ Complex Research Programs** | 5 copies of the Scientific Protocol and Insurance CertificateClinical Trial Registration Number and public register details |  |  |  |
| **Ionising Radiation Certificate** | Required? (*if so*, provide 5 copies) |  |  |  |
| **Working with Children clearance** | Required? (*if so*, attach to each copy of the application) |  |  |  |

**When you are satisfied that your application is complete, PLEASE SUBMIT:**

* **1** **single-sided,** **signed** **original**, including all attachments

**(original or digital signatures)**

* **20** **double-sided** hard copies of the signed original, including all attachments
* **1** **electronic copy** of the signed original, including all attachments:

**Please scan and email these through as one document, not as multiple attachments**

**TO:** Secretariat Support

 Central Australian Human Research Ethics Committee

 **cahrec@flinders.edu.au**

**By courier:** Secretariat Support

 CAHREC

Centre for Remote Health

 cnr Simpson and Skinner Sts

 ALICE SPRINGS

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