

MASTER PARTICIPANT INFORMATION BRIEF



INFORMATION SHEET (THIS IS FOR YOU TO KEEP)

Title	<i>Integrating Pharmacists within Aboriginal Community Controlled Health Service (ACCHSs) to improve Chronic Disease Management Project (IPAC)</i>
Short Title	<i>Putting Pharmacists into ACCHSs</i>
Project Sponsor	<i>James Cook University</i>
Coordinating Investigators	<i>Associate Professor Sophia Couzos (JCU), Ms Deb Bowden (PSA), Mr Mike Stephens (NACCHO), Ms Dawn Casey (NACCHO)</i>
Evaluation Team	<i>Prof Rhondda Jones (JCU), Dr Emily Callander (Griffith Uni), Dr Erik Biro (JCU), Dr Deborah Smith (JCU), Prof Bev Glass (JCU), Dr Robyn Preston (JCU), Ms Priscilla Page (JCU), Mr Donald Whaleboat (JCU), Assoc Prof Michelle Belling (JCU), Ms Nicole Bates (JCU), Mr Mark Thomas (JCU), Dr Nadia Lusi (VACCHO), Dr Elizabeth Moore (AMSANT), Mr Roderick Wright (QAIHC), Dr Katie Panaretto, Dr Douglas Boyle (UniMelb).</i>
Location	

What is the IPAC Project?

Our Aboriginal Community Controlled Health Service [ACCHS] has put a Pharmacist in this clinic for 15 months as part of the IPAC Project. The Pharmacist will help people by talking with them about their medicines and health. In this project they will not give out medicines. They will be part of the clinic like other staff.

This Project will help the Government to know if ACCHSs should be given money for a pharmacist to stay on in the clinic like other staff.

Do I have to take part? How will it work?

You are invited to take part in this project. If you don't want to, you can say no. This will not affect your health care at this clinic. A doctor, nurse, or health worker will ask some people coming to this clinic if they want to see the Pharmacist to help them with their medicines. A staff member will tell you about this Project and ask if you want to take part. You will then be asked to sign a consent form. You may see the Pharmacist straight away or make an appointment for a later time.

The Pharmacist will ask you about your medicines and your health. This is to find out how to make it easier for you to take the right medicines. The pharmacist will work with the doctor and other staff about your medicines, and will see you again to help you as much as possible. You can still see the Pharmacist even if you say no. If you decide to take part and later change your mind, you can withdraw from the project at any time. You can tell the Pharmacist or a staff member in the ACCHS that you no longer wish to take part.

Who is running the Project?

Aboriginal leaders in many organisations have all supported this Project. This ACCHS has said how this Project will run in this clinic.

Ethics approval has been received from the St Vincent's Hospital Melbourne Human Research Ethics Committee and this means that the project has been checked as safe and fair for people living in this part of Australia. This and other committees will watch over this Project. Aboriginal leaders and peoples from ACCHSs involved in this Project are also watching over this Project.

Who can be in this Project?

People coming to this ACCHS for a good while can be part of it if they are over 18 years of age, and if they have a health condition like diabetes, heart disease or other disease that means they need to take a lot of medicines. To be part, you must be able to show that you understand and agree that information about your health will be collected when seeing the Pharmacist.

What does taking part in this Project involve?

If you agree to take part, you will be seen by the Pharmacist in the clinic who will check your medicines and make sure they are the right ones for you. They will ask if you would like a full check of your medicines in the clinic, or at home, or a place that is best for you. The Pharmacist will listen to you and help you to get what you need

You can see the Pharmacist as many times as you like, whenever you like, and to ask for help about anything to do with your medicines. The Pharmacist will check how you are going, and may ask to see you in again. You will not need to pay any money for this service.

How will information be collected?

The information we need will already be in your clinic health record. It will just be copied from the record and include information from 12 months before you saw the pharmacist and information after you saw the pharmacist. No information about your name, date of birth, Medicare number, or any other personal information, or who you are, will be copied from your records. Your information will just be given a number and not a name. Information will be collected about your health, prescriptions, clinic visits, and Medicare information. Some information about people like their gender, age, Aboriginality, being a pensioner, and if they smoke will also be collected. The information that is collected will only be used for this project.

Are there any risks or benefits to me from taking part?

The Pharmacist is a qualified and registered health professional who has also been trained to work in this ACCHS. The risks are the same as if you saw a Pharmacist in a Pharmacy, except that you will be seeing them in this clinic.

Who can I talk to for more information or to make a complaint?

If you would like to know the results of this project or if you have any worries you can talk to staff at ACCHS. If you have any other worries, or need more information or would like to make a complaint, you can contact the NACCHO Project Lead: Mike Stephens, Tel: 02 6246 9300; Email: mike.stephens@naccho.org.au. Other Project staff to contact include: Deb Bowden from the Pharmaceutical Society of Australia: Tel: 02 6283 4740; Email: Deb.Bowden@psa.org.au. You can also contact the NACCHO Deputy Chief Executive Officer: Ms Dawn Casey at dawn.casey@naccho.org.au.

You can contact the Ethics Committee with any concerns about the safety and fairness of the Project at: Executive Office of Research, St Vincent's Hospital Melbourne, Tel: 03 9231 2394, or email: research.ethics@svhm.org.au:

Thank you on behalf of the IPAC Project Team.

The **IPAC Project** is the *Integrating Pharmacists within ACCHSs to improve Chronic Disease Management Project (IPAC)*. The Project Partners and Project Operational Team for the **IPAC Project** include: The National Aboriginal Community Controlled Health Organisation (NACCHO); Pharmaceutical Society of Australia, and the College of Medicine and Dentistry, James Cook University. **Evaluation Team** members include the Project Partners, and the Victorian Aboriginal Community Controlled Health Organisation (VACCHO); Queensland Aboriginal and Islander Health Council (QAIHC); and the Aboriginal Medical Services Alliance in the NT (AMSANT). The Project Reference Group includes representatives of NACCHO, Affiliates and ACCHSs.

MASTER PARTICIPANT CONSENT FORM



The IPAC Project has put a qualified Pharmacist into the clinic of this Aboriginal Community Controlled Health Service for 15 months. The pharmacist will help people with their medicines and health. The project is looking to see if the health of people seeing the pharmacist gets better over time.

1. _____ has explained the IPAC project to me including:

- ☐ The purpose of the Project
- ☐ Who is funding the Project
- ☐ What participation in this Project involves
- ☐ What the risks and benefits of participation are
- ☐ How some information about my health will be collected, and how I will not be able to be identified
- ☐ How this information will be stored and protected
- ☐ Who owns the information collected in this Project
- ☐ How this information will be used
- ☐ That I can choose not to participate, or stop participating, at any stage (and how) without affecting my current or future health care
- ☐ How to contact the Project leader to ask questions about the Project
- ☐ How to contact the Ethics Committee to make a complaint about the ethical conduct of the Project.

2. I have been given a Participant Information Sheet describing all the above points, or someone has read it to me in a language I can understand.
3. I understand all the above points and have been able to ask questions about anything that is unclear.
4. I agree to receive care for my health from the pharmacist in this clinic.
5. I understand I do not have to pay money for this service.
6. I agree that my information collected by this Project can be used for the purposes described.
7. I freely give my consent for participation in the IPAC Project.
8. I understand that I will be given a signed copy of this document to keep.

(Participant)

(Signature of Participant)

(Date)

(Witness)

(Signature of Witness)

(Date)

(Team member)

(Signature of Team member)

(Date)

The **IPAC Project** is the *Integrating Pharmacists within ACCHSs to improve Chronic Disease Management Project (IPAC)*. The Project Partners and Project Team Steering Committee for the **IPAC Project** include: The National Aboriginal Community Controlled Health Organisation (NACCHO); Pharmaceutical Society of Australia, and the College of Medicine and Dentistry, James Cook University. *Evaluation Team* members include the Project Partners, and the Victorian Aboriginal Community Controlled Health Organisation (VACCHO); Queensland Aboriginal and Islander Health Council (QAIHC); and the Aboriginal Medical Services Alliance in the NT (AMSANT). The Project Reference Group includes representatives of NACCHO, Affiliates and ACCHSs.

MASTER SITE PARTICIPATION BRIEF



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Location	<i>[Name of ACCHS]</i>

What is the IPAC Project?

IPAC stands for 'Integrating Pharmacists within Aboriginal Community Controlled Health Service (ACCHSs) to improve Chronic Disease Management' Project.

This project will explore if including a registered non-dispensing practice pharmacist as part of the primary health care team within Aboriginal community controlled health services (ACCHSs) leads to improvements in the quality of the care received by Aboriginal and Torres Strait Islander peoples. The project will explore improvements in prescribing by doctors, if patients are more likely to take their medicines, and if indicators of their health are improving over time, by measuring these factors before and after the pharmacist is appointed. Practice pharmacists will work with the doctors and other health staff in each ACCHS for a period of 15 months per service, in Vic, Qld and the NT.

Practice pharmacists will provide relevant healthcare activities within their scope of practice to patients. They will also provide education and training to existing staff within the services (as appropriate), improve relations with community pharmacies to overcome barriers that patients may face in accessing medicines, and assist in managing medications at transitions of care (such as discharge from hospital). This project will also explore the cost-effectiveness of pharmacist integration within ACCHSs.

How did this Project come about?

The Project was developed at the request of the National Aboriginal Community Controlled Health Organisation (NACCHO, representing ACCHSs across Australia) and the Pharmaceutical Society of Australia (PSA, representing pharmacists). The Project is a tripartite partnership between NACCHO, PSA and James Cook University (JCU). Participants include Affiliates of NACCHO in Vic, Qld, and the NT, up to 22 ACCHSs in these jurisdictions, practice pharmacists, and patients who will receive healthcare support from a pharmacist.

Community-based participatory research principles and methods are used to make sure there is appropriate Aboriginal governance over this Project.

Why is this Project important?

Aboriginal and Torres Strait Islander peoples experience a much higher burden of chronic disease due to cardiovascular, diabetes, and other health problems, and yet have poorer access to needed medicines.¹² Adverse health outcomes from these illnesses are preventable

if prescribing quality is improved, and patients are better supported with medicines use, which is a key health equity issue.

Non-dispensing pharmacists are not currently funded consistently or reliably to work within primary health care settings in the public health sector in Australia. Despite this, several ACCHSs across Australia have innovatively sourced funds and/or developed partnerships with community pharmacy's to source pharmacists in non-dispensing roles. This project is modelled on these pharmacists' roles and on international research evidence. There is extensive global evidence that practice pharmacists co-located within general practice clinics can enhance chronic disease management and quality use of medicines.³

The NACCHO and the PSA have promoted the need for this project for many years. The project will help the Australian Government make decisions about future funding and the role practice pharmacists may play as members of primary health care teams within ACCHSs and potentially other settings in Australia.

What is the aim of this project?

This project aims to improve quality of care outcomes for Aboriginal and/or Torres Strait Islander adult patients with chronic disease by integrating a practice pharmacist within the primary health care team of ACCHSs. This means the Project will investigate:

- Improvements in health measures of those patients who have been receiving support from a pharmacist and who agree to participate in the Project;
- Improvements in:
 - prescribing so that medicines patients are taking are appropriate for them and their individual healthcare needs;
 - patient adherence to medicines;
 - health service utilisation of Medicare;
 - relationships with and perceptions of stakeholders (ACCHSs staff; community pharmacies; pharmacists);
- The cost-effectiveness of the intervention, which will investigate the costs of the pharmacist service and measures of effectiveness such as increased Medicare utilisation (as a marker of increased patient access to healthcare services towards equity).

Does this project have ethics approval?

Ethics approval has been received from a Victorian Human Research Ethics Committee (HREC). This is the St Vincent's Public Hospital HREC in Melbourne. This HREC participates in National Mutual Acceptance of ethics. This means that the review of this committee in Victoria may be acceptable to other HRECs. Acknowledgement from JCU has also been received. This Project will also seek ethics review from two other HRECs in the Northern Territory. These are the:

- Menzies School of Health Research HREC
- Central Australian HREC

As this project is to be run in Qld, Victoria and the NT, ethics review is required from all these jurisdictions.

How is the Project funded?

The Australian Government under the Pharmacy Trials Program of the 6th Community Pharmacy Agreement has funded the project for 29 months.

Governance

The Project Partners and the Project Operational Team

This project is a partnership between the PSA, NACCHO, and JCU (College of Medicine and Dentistry), guided by a Memorandum of Understanding that outlines communication and governance processes.

The PSA, as the lead agency, is responsible for managing the Head Agreement with the Department of Health, and service agreements with partners and ACCHSs, and will coordinate the appointment of practice pharmacists, their recruitment, selection, placement, and training. The NACCHO will provide Aboriginal governance leadership for the project and coordinate all communication with ACCHSs, Affiliates and the NACCHO Board. JCU will undertake the project evaluation, having developed the research methodology based around a pragmatic, community-based participatory research model.

The Project Operational Team is made up of the project partners and is Chaired by the Deputy CEO of NACCHO, Ms Dawn Casey.

Steering Committee

The Operational Team will report to this group as this is made up of representatives of the Project partners, the Department of Health, the Pharmacy Guild of Australia and external experts.

Members of the Evaluation Team

The Project Partners are members of the evaluation team as are other Aboriginal community representative bodies. These are the Victorian Aboriginal Community Controlled Health Organisation (VACCHO); the Queensland Aboriginal and Islander Health Council (QAIHC), and the Aboriginal Medical Services Alliance in the NT (AMSANT). These organisations are NACCHO Affiliates and will be responsible for state-based service support to registered ACCHSs, and provide guidance to the project as members of the evaluation team.

Project Reference Group

State and Territory Affiliates of NACCHO (QAIHC, VACCHO and AMSANT) will be members of the Project Reference Group. Participating ACCHSs will also be invited to be members of the Project Reference Group managed by NACCHO. The Chair of the Project Reference Group will be a nominated member of the NACCHO Board of Directors. This group will meet by teleconference or web-based platforms.

Aboriginal governance and leadership

The way in which these groups communicate and link with each other is shown in Figure 1 and 2. The Project respects and acknowledges Aboriginal governance principles, and ACCHS sector leadership and involvement.

Figure 1. Governance and partnership structure of the IPAC project

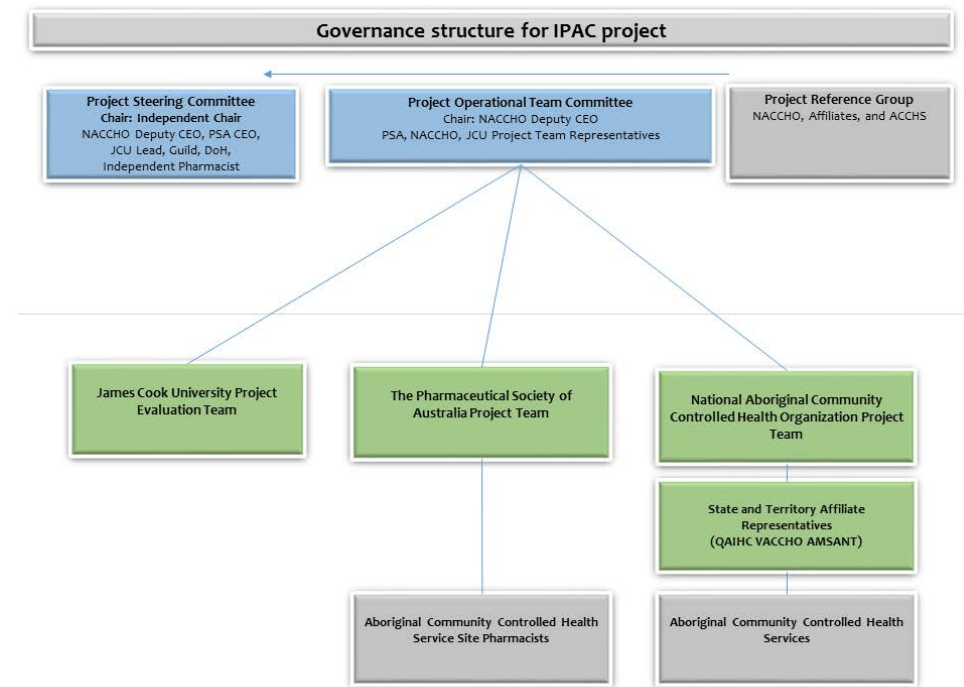
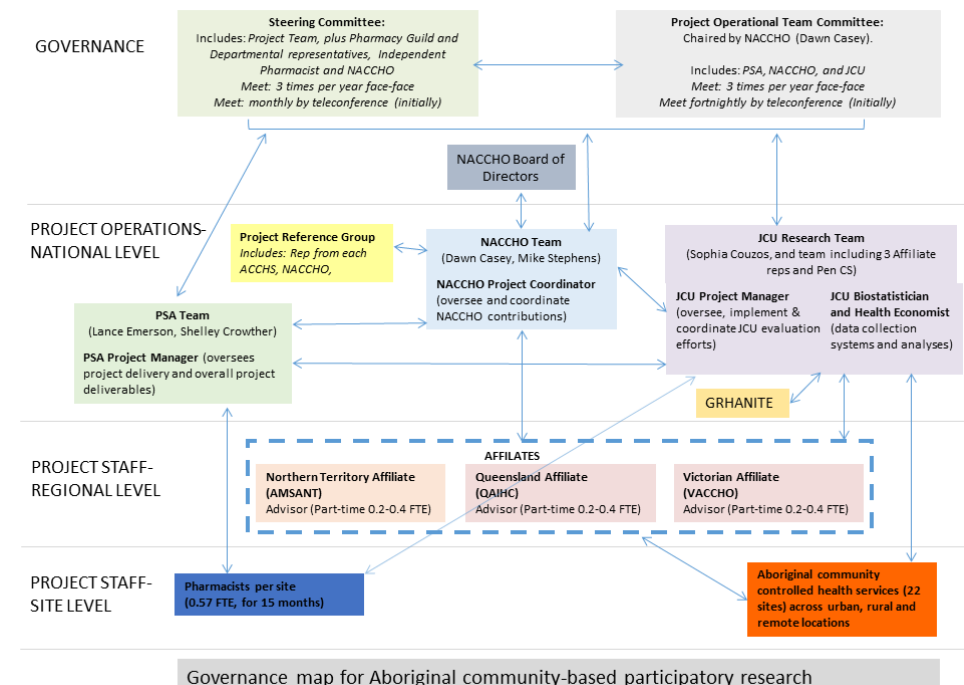


Figure 2. Governance map for the IPAC project.



What is the design of this project?

The project partners are committed to undertaking the Project to ensure clear benefits to ACCHSs, and to ensure acceptability and sustainability of the intervention within ACCHSs.

The project is a pre and post study where the pharmacist intervention will be added to standard primary health care practice within ACCHSs. Information will be collected from the

time the pharmacist starts until they finish, and this will be compared with information from 12 months before the pharmacist started.

The parts of the project

There are three project phases over a 29 month project duration: Phase 1: Establishment (4 months); Phase 2: Implementation/intervention (19 months); Phase 3: Analysis and Reporting (6 months). The project is scheduled to be completed by April 2020. ACCHSs will be invited in stages (tranches) and will therefore be staggered. This is so that the project can give time to each service to get them ready for the project.

The selection of project sites

The project is inviting ACCHSs in geographically diverse settings in Vic, Qld, and NT. Up to 22 ACCHSs will be able to participate. ACCHSs need to meet certain eligibility criteria to participate as project sites.

The eligibility criteria for ACCHSs is:

- The ACCHS employs at least one (1) full-time- equivalent (FTE) general practitioner per clinic who is able to prescribe medicines to clients of that organisation.
- The ACCHS does not currently employ a non-dispensing practice pharmacist at the participating clinic.
- The ACCHS uses a clinical information system such as Communicare, Best Practice, and Medical Director.
- The ACCHS has participated in continuing quality improvement and reporting on the national Key Performance Indicators for at least 24 months through the use of electronic data extraction tools.
- The ACCHS is participating in the *Quality Assurance for Aboriginal and Torres Strait Islander Medical Services* (QAAMS) program, if it is conducting 'point of care' testing.
- The ACCHS agrees to download the GRHANITE data extraction tool into one computer within the practice, adhere to program business rules/protocol and guidelines, data provision requirements, and patient/service consent requirements for the evaluation of the program.
- The ACCHS can provide the practice pharmacist access to a private consulting room on the clinic premises that has access to the clinical information system used by the practice.
- The ACCHS can allocate a staff member who will act as a 'go to' person to assist the practice to obtain informed patient consent.
- The ACCHS is a member of NACCHO, and the relevant NACCHO State/Territory Affiliate.
- The ACCHS is an accredited practice in accordance with the RACGP Practice Standards.
- In non-remote locations, the ACCHS must be participating or eligible to participate in the PBS co-payment measure (practice incentive program).
- In remote locations, the ACCHS must be eligible to participate in the remote Section 100 arrangements for the supply of pharmaceutical benefits

These criteria have been developed with Affiliate input to suit most ACCHSs in Qld, Vic, and the NT, and to make the project as 'real life' as possible. It is important that ACCHSs have clinical information systems (CIS) that the pharmacist can use like other health staff. Only the listed clinical information systems can work with the GRHANITE™ tool to collect information. (GRHANITE is explained later in this document).

The project will recognise the diversity of Aboriginal peoples and Torres Strait Islanders and models of care across Australia, and will select ACCHSs in urban, regional and remote areas.

This is so that the project can understand the many ways that ACCHSs may utilise the pharmacist in their clinic.

How will ACCHSs be invited to take part?

ACCHSs will be invited to participate in the project by NACCHO and Affiliates through an 'expression of interest' process. The 'expression of interest' process will explain to ACCHS the process that will be used for site selection.

The Project Operational Team, Chaired by the NACCHO Deputy CEO will review the expressions of interest and decide if a temporary Panel made up of Affiliate representatives is necessary to select the most suitable sites to participate in the project. As the recruitment process for sites will be staggered, this process will be repeated.

When NACCHO receives an expression of interest from an ACCHS, and the ACCHS is agreed to being a suitable site, the NACCHO Project Coordinator will contact the ACCHS and explain the project further to provide instructions on the process required to establish the site participation.

Formal participation of ACCHSs

After this consultation, a Site Agreement, Site Consent form, and Site Participation Brief (*this document*) will be provided to the ACCHS. Once this is signed and agreed, the project officers will arrange for practice pharmacist recruitment and placement within the ACCHS.

A visit to the ACCHS will be arranged to undertake a 'Needs Assessment' and a 'Health Systems Assessment' just before, or at the time that the practice pharmacist commences (these are explained later in this document).

How will each ACCHS benefit from this project?

Each service will be offered a practice pharmacist (aggregated 0.57 FTE across 22 sites each for 15 months duration) under a service agreement with the PSA. This will enhance the medicines-related workforce capacity of the ACCHS. Practice pharmacists are registered to work within their scope of practice and will have a non-dispensing role. The appointments will include salary, training, and the provision of supportive resources.

In the short-term, Medicare claims for medications-related, preventive care and chronic disease care may increase. The practice pharmacist will support other staff with quality prescribing and medicines use. The relationship with community pharmacies in the local area may improve if pharmacies' are helped to provide more appropriate services to the local community. Relationships between the ACCHS, local hospitals and other care providers may improve with communication between care providers when it pertains to the medicines that patients are taking.

These short-term benefits have potential for long-term gains for the sector as a whole. The project will provide the Australian Government with the evidence-base (biomedical, process, and economic evaluations) for the development of national health policies to potentially support on-going resourcing for practice pharmacists integrated within ACCHSs.

What is the role of the Affiliates in this Project?

NACCHO is a project partner and will maintain Aboriginal governance over this project. Affiliates are also participants in this project. They will be providing support to ACCHSs through funded project officer positions (0.2-0.4 FTE). The ACCHS will be notified of the name and contact details of the Affiliate staff to contact if and when the service needs to.

What is the pharmacist's role in the ACCHS?

The pharmacist employed within the ACCHS will deliver medication advice and education to patients and staff. They will work to improve patient medication adherence, improve prescribing, tailor medications to best suit the patient in collaboration with the prescriber, and assist with/oversee medication management processes. They may provide health promotion, disease prevention, and assist patients with chronic disease self- management and more judicious use of medicines.

The pharmacist will be required to respond to medication enquiries from patients and health professionals such as general practitioners and Aboriginal and Torres Strait Islander Health Workers/Practitioners, conduct staff education, review prescribing, mentor new prescribers, participate in case conferences, liaise across health sectors, undertake medication management reviews, and evaluate drug utilisation to ensure optimal therapy. As part of their collaborative work, an important element of the practice pharmacist's role is liaison with local community pharmacists to ensure continuity of care, and assist in medication management with transitions of care (such as when the patient is discharged from hospital).

Overall, there are 10 core roles targeting *patients*, and *health professionals and health systems*. These roles are all non-dispensing, for which practice pharmacists are registered to deliver. This is summarised in Table 1.

Whilst the project has developed these core roles for evaluation purposes, each participating ACCHS has the flexibility to utilise the services of the pharmacist according to service and client priorities. Practice pharmacists will be supported to adapt to cultural ways of delivering primary health care within each service. The project will aim to document the diversity in pharmacist core roles and in the patient journey. This will be possible through qualitative evaluation, but also through pre-post Health Systems Assessments (this is explained later in this document). The practice pharmacist will be supported to adapt to their role as directed by the staff and CEO.

Most of the practice pharmacist's activity must be devoted to providing supportive clinical care to patients who are participants in this project.

Table 1. Summary of practice pharmacists core roles

SUMMARY OF PRACTICE PHARMACISTS CORE ROLES

Core Role #	Theme	Core activity
1 (a)	Medication Management Reviews	Pharmacist reviews the medication the patient is taking. The pharmacist initiates and facilitates a medication management review- which may be a Home Medicines Review (HMR) or a non-HMR (medication management review not conducted in the patient's home)
1 (b)		Pharmacist reviews the patient who had a HMR after 12 months and a Non-HMR after 3-6 months.
1 (c)		Pharmacist ensures the MMR is claimed by the practice when completed (as a DMMR item 900 or RMMR item 903)
2	Team-based collaboration	Pharmacist participates in clinic activities that support team-based chronic disease care plans, and cardiovascular (CV) risk assessment
3 (a)	Medication adherence assessment & support	Pharmacist assesses the medication adherence of the patient being seen
3 (b)		Pharmacist improves the patient's experience with their medicines
4	Medication appropriateness audit	Pharmacist assesses 'medication appropriateness and underutilisation of medicines' <u>as an audit of a sample</u> of patients with chronic disease.
5	Preventative health care	Pharmacist provides preventive interventions to patients

6	Drug Utilisation Review	Pharmacist conducts a DUR to audit and improve a priority issue at the service
7	Education and training	Pharmacist conducts education sessions at the service
8	Medicines information service	Pharmacist provides medicines related information to staff within the service and responds to clinician medicines enquiries.
9	Medicines stakeholder liaison	Pharmacist develops a written <u>stakeholder liaison plan</u> supporting engagement with community pharmacies.
10	Transitional care	Pharmacist facilitates care coordination with relevant hospitals; residential aged care facilities, etc.

Pharmacist's qualifications

Pharmacist's who will be able to work in ACCHSs will be required to have:

- current registration with the Australian Health Practitioners Regulation Agency (AHPRA) as a pharmacist;
- more than 2 years post-registration experience;
- medication review accreditation such as from the Australia Association of Consultant Pharmacy (AACP) or Society of Hospital Pharmacists of Australia (SHPA) or working towards accreditation;
- post-graduate clinical qualifications or demonstrated clinical experience (e.g. hospital or HMRs).

The need for post-graduate qualifications or accreditation will be dependent on ACCHSs preference regarding the applicant and an adequate supply of accredited and experienced pharmacist applicants.

The PSA confirms that the proposed activities are consistent with the existing scope of practice of pharmacists as defined by the PSA Competency Standards endorsed by the Australian Health Practitioner Registration Agency.

Training the pharmacist at the ACCHS

The PSA will deliver the training to practice pharmacists in partnership with NACCHO. Some of the training will be off-site (before the pharmacist starts) and some will be on-site (at the start of their placement in the ACCHS). The NACCHO Coordinator and PSA training facilitator will arrange a training time with the practice pharmacist and with the nominated ACCHS, so that on-site training can best suit the ACCHS.

To follow up training, pharmacists will also have access to structured pharmacist mentor program that will link them with a dedicated mentor pharmacist with experience in the ACCH sector and to the other practice pharmacists within the project.

What patients' are eligible to be participants in this project?

If the patient is aged 18 years of age and over and has the following conditions, then they are eligible to be a participant in this project:

- Cardiovascular disease (coronary heart disease, stroke, hypertension, dyslipidaemia and any other CV disease)
- Type 2 diabetes mellitus,
- Chronic kidney disease,
- Other chronic conditions that mean a patient is at high risk of developing medication-related problems (e.g. polypharmacy).

These conditions are selected because *most* of the mortality gap for Aboriginal and Torres

Strait Islanders is due to these chronic diseases. Optimizing medicines for people with these conditions can make an important impact on their health.

The consent of the patient will be required to participate in this project. Most of the patients attending ACCHSs are of Aboriginal and Torres Strait Islander origin (81%).⁴ Therefore, we expect most of the patients involved in this project will be of Aboriginal and Torres Strait Islander origin.

Patients who are regular patients of the service should be prioritised as pharmacists will make sure they follow-up these patients over time.

If a patient consents to be a participant, how may they benefit from this project?

These participants will have immediate access to an on-site pharmacist at no charge. The Pharmacist will check their medicines and make sure they are right for them. Some recommendations may require the prescriber to change medicines or their dose, or cease a medication, or start a necessary medication.

The pharmacist will help resolve problems the participant may have with taking medicines, storing them, and will assess for adverse effects. Participants will be offered medication review in the clinic, or at home, or a place that best suits them. Just like the doctors and other staff, the pharmacist will record the encounter and recommendations in the CIS so that the doctor and health team can read them and make any agreed prescribing changes. The pharmacist also has more time to spend on supporting participants with medications than the doctor has.

The Pharmacist will see participants again to provide them with ongoing support. The pharmacist may follow-up with other members of the primary healthcare team, including with community pharmacy, and depending on the participants needs, with the hospital for discharge medications. This intensive support may help to improve the health of the participant.

There are no other expectations on participants in this project. Personal details of participants are not collected at all, and the data being extracted for the project is completely de-identified. A *Participant Consent Form* and *Participant Information Brief* is available for the ACCHS and practice pharmacist to seek patient consent. Patient participation in this project is voluntary. If consent is not given, this will not affect the patient's routine treatment, or their relationship the clinic, and the patient will still be able to be referred to the Pharmacist.

If a patient consents to be a participant, how may this benefit the ACCHS?

If patients agree to be participants, this enables the ACCHS to collect information for the purpose of the project. The participation of the patient will assist the ACCHS to collect information to determine the clinical and cost-effectiveness of the practice pharmacist, and will support the clinic activity overall (with Medicare and staff education). The information will inform on whether the health of participants improves over time, compared to their health before they received the services of the pharmacist. The ACCHS may receive a site-specific report if they wish. If patient consent is not given, information cannot be extracted from the CIS for this project. Patient consent is therefore vital to assess the value of the practice pharmacist within ACCHSs.

How will patients be referred to the pharmacist in the ACCHS?

The staff within the ACCHS will need to be briefed about this project and the role of the practice pharmacist. The project will also seek the consent of general practitioners in the clinic

and provide them with an *information brief*. This *Site Participation Brief* can assist the ACCHS with informing other staff.

Patients attending the ACCHSs doctor, health worker or other healthcare provider will be invited to talk to a practice pharmacist. These staff can refer the patient to the practice pharmacist. NACCHO and the PSA will prepare some simple promotional material to help health staff with this referral, so that patients who are most in need and meet the inclusion criteria are offered the services of the pharmacist.

The practice pharmacist or a designated staff member will tell the patient about this Project (and provide the patient with the *participant information brief*) and ask them if they want to take part. They will then be asked to *sign a participant consent form*. They may see the Pharmacist straight away or an appointment may need to be made for a later time.

The practice pharmacists (with assistance from trained ACCHS staff) may also directly approach patients attending the clinic who meet the individual participant criteria. The process for participant recruitment will be flexible according to the preferred process recommended by the ACCHS. This can be arranged during the first site visit to the ACCHS (see later in this document).

How will our ACCHS seek patient consent?

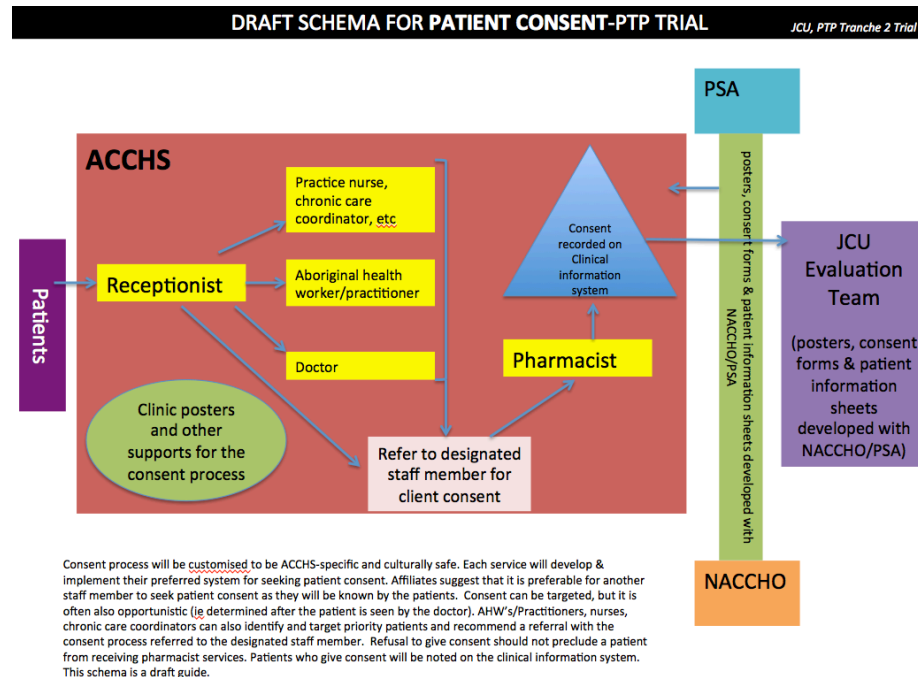
A suggested process for seeking individual patient consent has been developed in consultation with NACCHO Affiliates on the Evaluation Team. The process respects the systems that ACCHSs may wish and choose to adopt.

The practice pharmacist will be trained to seek the participant's consent. Training for seeking participant consent will also be provided to other staff who may be designated by the ACCHS to seek the participant's consent for cultural appropriateness reasons.

The participants consent form will then be signed and dated by the patient, a witness, and the designated staff member seeking patient consent. The consent form will be stored in a locked briefcase by the practice pharmacist until posted by registered post. It may be transmitted electronically to JCU after scanning. A written copy of the verbal information will be provided to the patient, including advice on how they may ask questions or make complaints about the project.

Consent will then be recorded on the clinical information system (CIS) by the practice pharmacist and GRHANITE will extract information only from consented patients. This suggested process is summarised in Figure 4.

Figure 4. A suggested process to seek patient consent.



How will participants be followed-up?

Practice Pharmacists will aim to follow-up participants using the usual clinic processes. Pharmacists will work with the existing staff in the ACCHS to follow-up participants in the same way used for all patients. Participants will need to be reviewed according to clinical needs and Medicare rules, and may include 3-monthly, 6-monthly or an annual review or more frequent review by the pharmacist.

The pharmacist will need to use the CIS within the ACCHS to record follow-up clinical details like other healthcare staff. The pharmacist will also record follow-up details in the pharmacist log-book as is appropriate for the type of review being conducted (such as medication appropriateness index measurements).

How many patients will ACCHS be asking to participate?

It is estimated that the practice pharmacist and the ACCHS may seek consent from about 350 people to be part of this Project and to see the Pharmacist over 15 months. This may vary considerably from service to service.

It is important for the ACCHS to encourage patients to be referred to the pharmacist early in the project. This is so that enough time is available to follow-up patients during the 15 months the pharmacist is employed in the project.

Are there any risks or benefits to patients from taking part?

The Pharmacist is a qualified and registered health professional who will be trained to work in this ACCHS. The risks to patients are no different to seeing a Pharmacist in a Pharmacy, except that patients will be seeing Pharmacists in this clinic. The Pharmacists will not be prescribing or dispensing medicines as they would in a Pharmacy. They will be working with the primary health care team in the ACCHS.

How will information for the project be collected?

The project has been designed to be acceptable and feasible to ACCHSs and practice pharmacists, by making most of the data collection a 'by-product' of service delivery. There are three main types of information that will be collected with the help of ACCHSs. Information will be collected from clinical information systems (CIS), pharmacist log-books (managed by the pharmacist), and from site visits to ACCHSs.

1. Deidentified information about patients who have consented (participants) will be collected from services clinical information systems (CIS), using an electronic data extraction tool known as **GRHANITE™**. ACCHSs will be supported to have the GRHANITE data extraction software installed in one personal computer in the clinic. This software will be installed in one workstation to minimise practice impact. When GRHANITE runs, it does so at a scheduled time and queries data from the practice database server. This is the only time GRHANITE communicates with the practice server. GRHANITE will extract weekly data from the CIS to the secure JCU repository. The ACCHS does not need to do anything to maintain that this program is working.
2. Practice pharmacists will also collect information about what they do through an **electronic log-book**. This system will be an online secure database requiring practice pharmacist secure log-in. It will be used by practice pharmacists to record deidentified daily activity. Each electronic log-book entry will be able to be interrogated by the JCU data custodian. The daily-recorded activity will refer to 6 core pharmacists roles. The electronic interface will be user-friendly to minimise the reporting burden of practice pharmacists.
3. **Health systems assessment, qualitative data, and cost-effectiveness analysis** data will be collected during visits to the ACCHS. Mainly the NACCHO Project Coordinator, will undertake visits to the ACCHS. A qualitative researcher will visit only three ACCHSs if they are invited by the service. The costs related to the employment of pharmacists will be sourced mainly from the PSA.

How does GRHANITE work and how secure is it?

GRHANITE™ strictly conforms to extract only data that is approved. It provides ethical and secure mechanisms for the provision of data from the CIS. If an individual gives their permission to be involved in a project, GRHANITE can read this consent information if it is recorded in the clinical notes. Patients who have not consented will not have their data interrogated, even if deidentified. This is an 'opt-in' consent process. Patient names, dates of birth, address or other identifying information are not extracted.

The data extraction from the CIS within the ACCHS will only extract deidentified data and then transmit it securely to the secure repository at JCU. The exported data is encrypted, and can only be decrypted at its final destination. This ensures transmission security. Data is deidentified as patients are assigned a unique patient ID. It is not possible for the project partners to reidentify any patient.

GRHANITE software will not operate if copied or moved from one computer to another. All installations require a unique authorising license. It is a nationally recognised tool as over 1000 health services across Australia have used/are using this for quality improvement and for research activity.

JCU will be the repository body responsible for the protection of data from loss, misuse and unauthorised access. A data custodian will be appointed (the biostatistician investigator). JCU will comply with the Code for the Responsible Conduct of Research (JCU) [This Code has been adapted from the Australian Code for the Responsible Conduct of Research [“the National

Code”], developed jointly by the National Health and Medical Research Council, Australian Research Council and Universities Australia, and published in 2007.⁵

What type of information will be collected by GRHANITE?

The information will be deidentified and only from consented patients (participants). The information will refer to periods 12 months before, and the periods after the pharmacist first provided support to the participants. This is summarised in Table 2.

Table 2. Deidentified patient information that will be extracted from clinical information systems (CIS) in the ACCHS

Measure	Detail
Patient characteristics	age, year of birth, sex, height and weight (for BMI), condition (diabetes, hypertension, dyslipidaemia, CHD, PAD, CVA, CKD, plus other disease (<i>in patients who fit the inclusion criteria with polypharmacy</i>), smoking status (history details: start/stop year), postcode, CTG status, ethnicity, Aboriginal and Torres Strait Islander status, DVA status, pension/concessional status, year of death.
Encounter/contact indices & other demographic measures	contacts with staff (different job roles), episodes of care (date of visit, reason for visit, duration, visit type), patient status/record status (active), created and updated dates and user who created and updated the record; consented patients; patients ID/MRN/UR number/chart No/record No
Biometric indices	Diastolic and systolic BP, HbA1c, lipids (HDL, LDL, TG's, and TC), CV absolute risk assessment (levels and risk), ACR, e-GFR,
Prescribing indices	All medications (including PBS drug code); all information contained within prescriptions (route, strength, formulation, quantity); date of the script being generated, including ceased/delete date; deleted flag (if any) and reason for delete or ceased; created and updated dates, and user (job role) who created and updated the record. This information is for both current medications and past medications.
Dispensing indices	All medications (including PBS drug code); all information contained within prescriptions (route, strength, formulation, quantity); date of the medicine being supplied and dispensed; user (job role) who created and updated the record. This information is for both current medications and past medications.
Measures of health service utilisation:	
Medicare Benefits Schedule indices	900 (DMMR or HMR), 903 (residential aged care DMMR or HMR), 721 (GPMP), 732 (GPMP review 3 months later), 715 (Health Check) and other MBS items related to the evaluation of pharmacist activities; record status, created and updated dates, and user (job role) who created and updated the record, item billing amount.
Non-HMR data (out-of home interviews)	non-HMR flagged in CIS will link this to the above variables (<i>to be recorded by the pharmacist</i>).
Measures of medication adherence	<ul style="list-style-type: none"> Electronic measures of medication adherence (<i>to be calculated by the evaluators</i>) Medication Adherence (<i>to be recorded by the pharmacist</i>)

ACR= albumin-creatinine ratio; BP= blood pressure; CIS= clinical information systems; CKD= chronic kidney disease; CTG= Close The Gap; CV= cardiovascular; CVA= cerebrovascular disease; DET= data extraction tool (GRHANITE); DMMR= Domiciliary Medication Management Review; DVA: Dept of Veterans Affairs; e-GFR= electronic glomerular

filtration rate; GPMP= General Practice Management Plan; HDL= high density lipoprotein; HMR= Home Medications Review; LDL= low density lipoprotein; MAI= Medication Appropriateness Index; PAD= peripheral artery disease; TC= total cholesterol; TG= triglyceride

What type of information will be collected by the pharmacist in the log-book?

The pharmacist will record their daily activity in the log-book. This will include information about education sessions they provided to staff, adhoc advice provided and any evidence this led to an outcome, the development of any resources for patients or the ACCHS, whether the pharmacist developed a plan to liaise with community pharmacy (and details of that plan), and the number of medicines reconciliations from stakeholders like hospitals.

In particular, the pharmacists log-book will enable practice pharmacists to record the results of medication assessments for each of 30 participants. Of the participants seen by a practice pharmacist, 30 participants per site will have their medications intensively appraised as part of the medication management review.

No personal information about participants is contained in the log-book. The participant does not need to be present for the medication assessment as it is an audit of the participants medications held in the CIS.

The pharmacist will only record the unique 'patient ID' to enable matching of the medication assessment audit of 30 participants to the participant data extracted through GRHANITE.

The practice pharmacist will communicate the findings of the medication assessment for the participant to the prescribing team within the ACCHS so that appropriate clinical action is taken. Practice pharmacists will ensure that the assessment takes account of additional clinical information such as an assessment of the participant's absolute cardiovascular risk when assessing their medications.

Practice Pharmacists will follow-up participants as per usual clinic processes. These follow-up mechanisms may vary from service to service (see above).

What type of information will be collected during the site visits?

Every participating ACCHS site will be visited at least twice during the project.

1. The 'needs assessment' visit (see 'what will happen during the first visit').
2. To conduct a 'health systems assessment' (HSA):
 - at the time of, or just prior to the appointment of the pharmacist, and
 - repeated towards the end of the implementation phase (month 12-15).

The NACCHO Project Coordinator will conduct visits and assessment with assistance from Affiliate staff. The needs assessment and health systems assessment will be conducted at the first visit.

The 'needs assessment' will collect information about what the ACCHS may need to support the practice pharmacist to work in that clinic. This will be used to help the pharmacist to get started.

The 'health systems assessment' will source information about the ACCHS. Each ACCHS is different in many ways. The project needs to understand how many staff (and types) are employed within the ACCHS, the total service population, the total service budget, Aboriginal governance structures, health services on offer, quality improvement processes, models of care such as outreach, if home medicines reviews are conducted and how, type of CIS used, recall systems in place, the adequacy of existing communication with the hospital, and community pharmacy/ies, medicines access information, use of point of care testing, regional

services available such as specialist and allied health visits, and how the ACCHS will implement and define the core roles of practice pharmacists.

A meeting with key informant staff in a focus group setting will be needed to undertake the health systems assessment. This information will be collated in a summary report for the ACCHS to use for any quality assurance activity.

What type of information will be collected for qualitative analysis?

Three ACCHSs will be invited to participate in a qualitative evaluation of the Project in mid-late 2019. ACCHSs will be asked if they will support focus group discussions with certain patients, Aboriginal health workers/practitioners, and with the pharmacist on site. These meetings will be fully catered and will be conducted in ways to minimize clinic disruption. ACCHSs will be contacted closer to that time to explain what that might involve.

What will happen during the first visit to the ACCHS?

The 'needs assessment' visit to the ACCHS will elicit the type of support needed by the ACCHS so that the practice pharmacist may best be integrated within the service. The visit will also assist the ACCHS to establish their preferred system to seek patient consent, and ensure the pharmacist can use the CIS, has a space to consult with patients, and the CIS is set to accept the 'job-role' for the pharmacist (this is necessary for the GRHANITE data extraction). A 'health systems assessment' may also be undertaken at this visit (see above).

The NACCHO Project Coordinator will make contact at this visit with the nominated ACCHS staff member who will act as a 'go to' person. Together with the nominated 'go to' person/s and relevant ACCHS staff, a project consent pathway and process that is responsive to the local ACCHS' model of care will be planned. A second 'go to' person may also need to be identified by the ACCHS and Coordinator as contingency for leave, resignation or movement between clinics or roles.

The NACCHO Project Coordinator will ensure that the service has adequate promotional material and strategies to engage both ACCHS staff and clients.

Who owns the GRHANITE information?

The raw (unanalysed) data collected from the GRHANITE data extraction is owned by the ACCHS even though it will be used, analysed and stored safely by JCU. Details regarding this is included in the service agreement with the ACCHS for this project.

Intellectual Property

Details regarding Intellectual Property of the Project will be included in the Service Agreement with the PSA.

Use of information collected by the Project

The information collected from this project will be used to prepare reports to the Australian Government on 'quality of care' outcomes (the project objective) that arise from integrating a practice pharmacist within ACCHSs. The reports will assess change in the:

- quality of prescribing,
- quality of medicines support through indicators of health service utilization,
- quality of the patient, service and stakeholder experience, and
- ultimately an effect of these improvements on biometric indices as a measure of health outcome.

The reports will also assess the cost-effectiveness of the practice pharmacist within ACCHSs.

The data analysis will also be able to provide ACCHSs and Affiliates with local level and aggregated data. Most analyses at this level would not be meaningful because the number of participants will be too small. However, the information will be aggregated at a national level for the NACCHO, Affiliates, ACCHSs, and the PSA, as well as the Australian Government. This will inform the development of health policy about practice pharmacists and the role they can play supporting Aboriginal and Torres Strait Islander peoples with chronic disease in Australian primary health care settings.

Health systems assessment summaries will also be able to be provided to ACCHSs for their use.

Security of information collected by the Project

As the leading research organisation, JCU (the repository body) will be responsible for the protection of data from loss, misuse and unauthorised access. The Data Custodian (Biostatistician: Erik Biros) will be responsible for this role.

Further, the Project Operational Team, Chaired by the Deputy CEO of NACCHO, will be consulted in all matters brought to its attention with regard to concerns about data security.

How will the collected information be transported to JCU?

Completed Site Consent Forms will be collected by the NACCHO Project Coordinator, scanned and sent electronically to the data custodian. Participant consent forms will be scanned by the practice pharmacist and electronically transmitted to the data custodian. The forms will be stored electronically in a secure computer under the management of the data custodian on the property of College of Medicine and Dentistry, James Cook University.

Information extracted using GRHANITE and from the Pharmacist log-book will be transmitted electronically and stored on password-protected internal server on JCU premises. Data accessed during the analysis phase will be stored in JCU-supported database applications only.

Health Systems Assessment (HSA) and Needs Assessment information collected from site visits, will be collected on paper-based forms, (or in electronic format) collected by the NACCHO Project Coordinator and will be transported in a locked briefcase, scanned and stored in electronic format in a secure computer under the management of the data custodian.

Where and for how long is the information going to be kept?

Data will be kept for a minimum period of 7 years from the end of the year of publication of the last refereed publication or other form of public release to an audience external to JCU.

Electronic data will be stored on password-secured databases only. Any paper-based documents will be scanned and stored electronically, and the paper documents stored in a locked cabinet in a secure room at JCU. The data custodian (Biostatistician- Erik Biros) will be responsible for data storage consistent with the JCU *Code for the Responsible Conduct of Research*.

After the minimum period of storage, the data may be considered for disposal if there is a written request to the Evaluation Lead, from both the NACCHO and the PSA for the disposal of the data. As the raw unanalyzed data extracted by GRHANITE is owned by the ACCHSs, JCU will seek instruction from NACCHO and each ACCHS as to the ongoing use or destruction of this data. The Evaluation Lead will authorize the data custodian to delete the data if this is instructed by NACCHO, in accordance with the JCU *Code*.

Who will be able to access this information?

Data will be accessible only to members of the Evaluation Team who will have a role in handling this information. From time to time, one member of the evaluation team (the

University of Melbourne HaBIC Research Information Technology Unit) may need access to the data-landing server at JCU to provide technical support services.

ACCHSs may request access to de-identified information from their service. These requests can be made to the Project Operational Team or its members, or directly through the NACCHO Affiliate or Project Officers involved in this project. The request must also include documentation of intended data use and must align with project objectives (the individual consent provided by each participant). Requests to access the data that *does not align* with the project objectives will need HREC approval. Similarly, Affiliates may request access to data at their jurisdictional level. This request must be in writing and align with the project objectives.

External requests from other organizations and research agencies not participating in this project to access data from this project will need to be submitted to the Project Operational Team. NACCHO will recommend that external agencies seek approval from Affiliates and from participating ACCHSs relevant to the request. Approval will not be granted for the release of data if it is not approved by NACCHO. There may be a need to seek approval from the Department of Health if this is a condition in the Head Agreement for this project. All external requests will need to have HREC approval prior to the release of this data.

What can we do if we have concerns about data security, research misconduct or complaints?

ACCHSs can report any breaches in data security or research misconduct or complaints to:

- project partners/staff,
- Affiliates,
- NACCHO directly, and/or
- Designated HREC representative.

Reports received by project staff will be forwarded to the Project Operational Team and the Deputy CEO of NACCHO.

What is the role of ACCHSs in this project?

The ACCHS will host the practice pharmacist who will be providing health services to the patients in the community. The pharmacist will effectively be an employee of the PSA, who will provide all employment support. This will minimise the administrative burden on the ACCHS so that the pharmacist and ACCHS can focus on effective service delivery from the start. NACCHO and respective Affiliates will have the capacity to liaise closely with PSA, ACCHS and the pharmacist to ensure that the pharmacist's roles are understood clearly by both parties.

The Head Agreement between the PSA and the Department of Health will influence the service agreement between the PSA and the ACCHS. The Service Agreement with the ACCHS will document the terms of participation including: Health Service Responsibilities and Financial Arrangements.

ACCHSs will be provided with a *Site Consent Form* that will need to be signed if the ACCHS agrees to be a participant in this project.

The NACCHO Project Coordinator will be available to ACCHSs to assist in understanding and delivering on their roles within the project. They may also work with their Affiliate representative to assist ACCHSs.

The following is a summary of the ACCHSs role as a participant in this project that will be negotiated with each ACCHS to be most appropriate for that service. The role of the ACCHS is:

- To nominate a 'go to' person to be a point of contact for the project staff.

- To support the practice pharmacist to use the CIS within the practice, and access the patient's clinical records in order to support patient care and make medicines-related recommendations to other health staff.
- To enable the CIS to recognise the practice pharmacist in their 'job role'. (The ACCHS will be assisted with this. This is so that the information can be collected about the work the pharmacist has done).
- To support the pharmacist to access a private consulting room to meet with patients.
- To support the practice pharmacist to have time to record their work and findings in the pharmacist log-book.
- To assist the practice pharmacist to work with other members of the health care team by sharing information about the project with other members of the team.
- To assist the pharmacist to prepare a workplan that best suits the model of care of the ACCHS.
- To host information for patients attending the practice by using posters and other health promotion material to promote patients to be participants in this project.
- To develop a participant consent process that is approved by the ACCHS involving the practice pharmacist and/or other staff in the ACCHS.
- To support site visits and support a focus group with relevant staff for 'health systems assessment' and 'needs assessment'.
- To support site visits and support focus groups with relevant staff for the qualitative evaluation if the ACCHS wishes to volunteer as a case study site (further information about this will be provided to ACCHS to make a decision in 2019).
- Any other matters that are relevant to the work of the practice pharmacist that the ACCHS may wish to consider. (Examples include mechanisms for home medicines review, or use of point of care testing, etc).

What support will ACCHSs receive in this project?

Each ACCHS that participates in the project will receive:

- The services of an on-site registered practice pharmacist for a 15-month duration.
- Administration of pharmacist employment and contract to be provided by PSA.
- The opportunity to select their preferred practice pharmacist.
- A 'Needs Assessment' site visit to ascertain any specific needs of ACCHS.
- A facilitated 'training' on-site visit to support and prepare the practice pharmacist within the primary healthcare team.
- Resources to support the practice pharmacist, such as medication management guides.
- A supportive mentor for the practice pharmacist (that will be managed by NACCHO and the PSA).
- Installation of the GRHANITE data extraction tool in the CIS and licence for its use for 15 months.
- Two site visits to explore Health Systems Assessment (one of these will be at the same time as the needs assessment visit).
- A Health Systems Assessment Report for ACCHS use for CQI.
- Involvement of a nominated staff member to be a member of the Project Reference Group in the project.
- Support from a nominated Affiliate officer involved in this project.
- Support from the NACCHO Project Coordinator during site visits and contact by email and phone.
- An opportunity to review project findings and provide feedback through ACCHS membership of the Project Reference Group.

- Customised reports specific to the participating ACCHS (if requested and if the data analysis is meaningful due to limitations with small participant numbers).

Each Affiliate that participates in the project will receive:

- Remuneration to participate in the project. This can be used to employ a part-time project officer (or to back-fill existing staff).
- Involvement of nominated staff as members of the Evaluation Team in the project.
- An opportunity to review project findings and provide feedback (through membership of the evaluation team and Project reference group).
- Customised reports specific to the jurisdiction (if requested).

How will ACCHSs find out the results of the Project?

ACCHSs will receive information about the Project through NACCHO communication mechanisms. The Project will finish at ACCHSs in late 2019. The ACCHSs will know the results in 2020. Other ways in which ACCHSs will be informed include:

- Through the Project Reference Group which will be provided with updates on progress with the project and extracts of reports arising from the project.
- Summary results to individual ACCHSs (pertaining to their own data) may be provided upon request to the Project Operational Team, although these may not be meaningful due to small participant numbers and the inability to undertake data analysis.
- Extracts of reports arising from this project will be summarized in plain language and disseminated according to usual NACCHO communication mechanisms, such as email, the NACCHO News, and NACCHO website, including communication with any relevant special interest groups supported by NACCHO.
- Presentations detailing progress and results will be communicated at NACCHO and/or Affiliate Conferences and Annual Meetings.

The findings of the project will also be reported for publication in articles and journals relevant to this project. There may also be presentations at conferences.

Reports will also be provided to the Australian Government, Department of Health, and through communication mechanisms used by the Pharmaceutical Society of Australia. NACCHO (as a project partner) will check this information before it is released.

Can ACCHSs decide to withdraw from this project?

ACCHSs and Affiliates that are participants reserve the right to withdraw their participation in the project in accordance with their service agreements. If an ACCHS site withdraws, the ACCHS will be asked to provide a written reason for the withdrawal to the PSA (for the contract) and the Project Operational Team. The ACCHS will be asked whether they agree to the continued use of the data collected in this Project prior to their withdrawal of Site Consent. The withdrawal of the Site from the project will mean the withdrawal of the site support specified in the service agreement (and explained above). The withdrawal of the Site will be reported to all relevant HRECs when the Project's annual report is due.

Who can the ACCHS contact for more information or to make a complaint?

The ACCHS can contact the NACCHO Project Lead: Mike Stephens, Tel: 02 6246 9300; Email: mike.stephens@naccho.org.au. Other Project staff to contact include: Deb Bowden from the Pharmaceutical Society of Australia: Tel: 02 6283 4740; Email: Deb.Bowden@psa.org.au. You can also contact the NACCHO Deputy Chief Executive Officer: Ms Dawn Casey at dawn.casey@naccho.org.au.

The Human Research Ethics Committees will continue to provide oversight as the project progresses. You can contact the Ethics Committee with any concerns about the safety and

fairness of the Project at: Executive Office of Research, St Vincent's Hospital Melbourne, Tel:
03 9231 2394, or email: research.ethics@svhm.org.au

Thank you on behalf of the IPAC Project Team.

The **IPAC Project** is the *Integrating Pharmacists within ACCHSs to improve Chronic Disease Management Project (IPAC)*. The Project Partners and Project Operational Team for the **IPAC Project** include: The National Aboriginal Community Controlled Health Organisation (NACCHO); Pharmaceutical Society of Australia, and the College of Medicine and Dentistry, James Cook University. **Evaluation Team** members include the Project Partners, and the Victorian Aboriginal Community Controlled Health Organisation (VACCHO); Queensland Aboriginal and Islander Health Council (QAIHC); and the Aboriginal Medical Services Alliance in the NT (AMSANT). The Project Reference Group includes representatives of NACCHO, Affiliates and ACCHSs.

¹ Pharmaceutical Society of Australia. *Guide to providing pharmacy services to Aboriginal and Torres Strait Islander people*. Jul 2014. <http://www.psa.org.au/download/guidelines/Guide-to-providing-pharmacy-services-to-Aboriginal-and-Torres-Strait-Islander-people.pdf>

² Couzos S, Murray R: Health, Human Rights and the Policy Process. In: *Aboriginal Primary Health Care: An Evidence-based Approach*. edn. Edited by Couzos S, Murray R. Melbourne: Oxford University Press; 2007: 29-63.

³ Tan ECK, Stewart K, Elliott RA, George J. Integration of pharmacists into general practice clinics in Australia: the views of general practitioners and pharmacists. *Int J Pharm Pract* 2014;22(1):28–37. At: <http://onlinelibrary.wiley.com/doi/10.1111/ijpp.12047/pdf>

⁴ Australian Institute of Health and Welfare 2016. Healthy Futures—Aboriginal Community Controlled Health Services: Report Card 2016. Cat. no. IHW 171. Canberra: AIHW.

⁵ JCU Code for the Responsible Conduct of Research (JCU) <https://www.jcu.edu.au/policy/research-management/code-for-the-responsible-conduct-of-research>

MASTER SITE CONSENT FORM



JAMES COOK
UNIVERSITY
AUSTRALIA



Pharmaceutical
Society of Australia

Name of Project: *Integrating Pharmacists within Aboriginal Community Controlled Health Services to improve Chronic Disease Management (IPAC) Project*

Name of Aboriginal Community Controlled Health Organisation: insert name of ACCHS

Project Leaders: Ms Dawn Casey, Mr Mike Stephens (NACCHO), Associate Professor Sophia Couzos (JCU), Ms Deb Bowden (PSA)

Evaluation Organisation: Evaluation Team led by the College of Medicine and Dentistry, JCU.

Project Sponsor: James Cook University (JCU)

I,can confirm that the

(insert name of Aboriginal Community Controlled Health Service) gives its consent to the above project, subject to the following conditions:

1. We have the right to withdraw our consent and cease any further involvement in this Project at any time without any penalty and without giving any reasons.
2. The purpose of the Project, as outlined in the attached Site Participation Brief has been explained, and we have had the opportunity to ask questions about the project. We have received satisfactory answers to our questions and have been given adequate time to consider the appropriateness of the project.
3. The Project Partners will need to obtain additional consent if there are any changes to the overall design of this Project.
4. The Practice Pharmacist, who will be employed by our service, will receive off-site and on-site training by a visiting facilitator from the PSA in consultation with NACCHO. This will be conducted in consultation with your nominated staff, and your Affiliate.
5. The Practice Pharmacist will be able use our clinical information system and access the information contained within it to allow them to undertake their clinical duties, and to support the data collection required for this Project including completing their Pharmacist Log Book.
6. Our ACCHS will receive at least two on-site support visits to assist our service to integrate the Practice Pharmacist into our health service team, and to collect data about our health service.
7. We agree to allow data to be extracted from our clinical information system using the GRHANITE™ Data Extraction Tool, for the purpose of evaluating this Project. This will occur only for individual participants who have consented for this to occur and be de-identified.
8. Our ACCHS will assist the Practice Pharmacist to set up appropriate systems within our ACCHS to obtain the written consent of individual participants in this Project. This includes nominating a dedicated 'go to' ACCHS staff member to assist in obtaining consent.
9. Data collected from our ACCHS, in its raw and unanalysed form, is owned by our ACCHS. It will be stored and managed by the Data Custodian at the College of Medicine and Dentistry (JCU) and adhere to all ethical requirements.
10. Any results from this Project that are published by the Project Partners will acknowledge the ACCHSs ownership of this data.

11. Any information that identifies this ACCHS or the Aboriginal and Torres Strait Islander community that it serves will not be used nor published without the written permission of the Board or CEO of this ACCHS.
12. This Project will not proceed until all required negotiation has occurred to the satisfaction of this ACCHS. This will include a legal Agreement with the PSA, described in the attached Site Participation Brief.
13. The ethical provisions relating to the health of Aboriginal and Torres Strait Islander peoples, as set out in NHMRC publications, will be complied with and this Project will not proceed until the St Vincent's Hospital Melbourne Human Research Ethics Committee has endorsed the Project.
14. We understand that if we have any complaints or questions concerning this Project we can contact any of the key contacts mentioned in the Site Participation Brief. This includes the St Vincent's Hospital Melbourne Human Research Ethics Committee with contact details as follows: Executive Office of Research, St Vincent's Hospital Melbourne, Tel: 03 9231 2394, or email: research.ethics@svhm.org.au
15. We understand we will receive a signed copy of this document and the Site Participation Brief to keep.

Signed on behalf of (_____ insert name of ACCHS _____)

Signature

Position in the organisation (Board Chair or CEO)

Date

Witnessed by Date

As the Contractor (PSA) and in this Project and on behalf of the Project Partners, I acknowledge the conditions set out above:

Name:

Signature..... Date

Witnessed by Date

The Project Partners, and Project Operational Team for the *Integrating Pharmacists within ACCHSs to improve Chronic Disease Management Project (IPAC)* include: The National Aboriginal Community Controlled Health Organisation (NACCHO); Pharmaceutical Society of Australia, and the College of Medicine and Dentistry, James Cook University. *Evaluation Team* members include the Project Partners, and the Victorian Aboriginal Community Controlled Health Organisation (VACCHO); Queensland Aboriginal and Islander Health Council (QAIHC); and the Aboriginal Medical Services Alliance in the NT (AMSANT). The Project Reference Group includes representatives of NACCHO, Affiliates and ACCHSs.

MASTER GENERAL PRACTITIONER PARTICIPATION BRIEF



Title	<i>Integrating Pharmacists within Aboriginal Community Controlled Health Service (ACCHSs) to improve Chronic Disease Management Project (IPAC)</i>
Short Title	<i>Putting Pharmacists into ACCHSs</i>
Project Sponsor	<i>James Cook University</i>
Coordinating Investigators	<i>Associate Professor Sophia Couzos (JCU), Ms Deb Bowden (PSA), Mr Mike Stephens (NACCHO), Ms Dawn Casey (NACCHO)</i>
Evaluation Team	<i>Prof Rhonda Jones (JCU), Dr Emily Callander (Griffith Uni), Dr Erik Biro (JCU), Dr Deborah Smith (JCU), Prof Bev Glass (JCU), Dr Robyn Preston (JCU), Ms Priscilla Page (JCU), Mr Donald Whaleboat (JCU), Assoc Prof Michelle Belling (JCU), Ms Nicole Bates (JCU), Mr Mark (Joseph) Thomas, Dr Nadia Lusi (VACCHO), Dr Elizabeth Moore (AMSANT), Mr Roderick Wright (QAIHC), Dr Katie Panaretto, Dr Douglas Boyle (UniMelb).</i>
Location	<i>[Name of ACCHS]</i>

What is the IPAC Project?

IPAC stands for 'Integrating Pharmacists within Aboriginal Community Controlled Health Service (ACCHSs) to improve Chronic Disease Management' Project.

This project will explore if including a registered non-dispensing practice pharmacist as part of the primary health care team within Aboriginal community controlled health services (ACCHSs) leads to improvements in the quality of the care received by Aboriginal and Torres Strait Islander peoples. The project will explore improvements in prescribing by doctors, if patients are more likely to take their medicines, and if indicators of their health are improving over time, by measuring these factors before and after the pharmacist is appointed. Practice pharmacists will work with the doctors and other health staff in each ACCHS for a period of 15 months per service, in Vic, Qld and the NT.

Practice pharmacists will provide relevant healthcare activities within their scope of practice to patients. They will also provide education and training to existing staff within the services (as appropriate), improve relations with community pharmacies to overcome barriers that patients may face in accessing medicines, and assist in managing medications at transitions of care (such as discharge from hospital). This project will also explore the cost-effectiveness of pharmacist integration within ACCHSs.

How did this Project come about?

The Project was developed at the request of the National Aboriginal Community Controlled Health Organisation (NACCHO, representing ACCHSs across Australia) and the Pharmaceutical Society of Australia (PSA, representing pharmacists). The Project is a tripartite partnership between NACCHO, PSA and James Cook University (JCU). Participants include Affiliates of NACCHO in Vic, Qld, and the NT, up to 22 ACCHSs in these jurisdictions, practice pharmacists, and patients who will receive healthcare support from a pharmacist.

Community-based participatory research principles and methods are used to make sure there is appropriate Aboriginal governance over this Project.

Why is this Project important?

Aboriginal and Torres Strait Islander peoples experience a much higher burden of chronic disease due to cardiovascular, diabetes, and other health problems, and yet have poorer access to needed medicines.¹² Adverse health outcomes from these illnesses are preventable if prescribing quality is improved, and patients are better supported with medicines use, which is a key health equity issue.

Non-dispensing pharmacists are not currently funded consistently or reliably to work within primary health care settings in the public health sector in Australia. Despite this, several ACCHSs across Australia have innovatively sourced funds and/or developed partnerships with community pharmacy's to source pharmacists in non-dispensing roles. This project is modelled on these pharmacists' roles and on international research evidence. There is extensive global evidence that practice pharmacists co-located within general practice clinics can enhance chronic disease management and quality use of medicines.³

The NACCHO and the PSA have promoted the need for this project for many years. The project will help the Australian Government make decisions about future funding and the role practice pharmacists may play as members of primary health care teams within ACCHSs and potentially other settings in Australia.

What is the aim of this project?

This project aims to improve quality of care outcomes for Aboriginal and/or Torres Strait Islander adult patients with chronic disease by integrating a practice pharmacist within the primary health care team of ACCHSs. This means the Project will investigate:

- Improvements in health measures of those patients who have been receiving support from a pharmacist and who agree to participate in the Project;
- Improvements in:
 - prescribing so that medicines patients are taking are appropriate for them and their individual healthcare needs;
 - patient adherence to medicines;
 - health service utilisation of Medicare;
 - relationships with and perceptions of stakeholders (ACCHSs staff; community pharmacies; pharmacists);
- The cost-effectiveness of the intervention, which will investigate the costs of the pharmacist service and measures of effectiveness such as increased Medicare utilisation (as a marker of increased patient access to healthcare services towards equity).

Does this project have ethics approval?

Ethics approval has been received from a Victorian Human Research Ethics Committee (HREC). This is the St Vincent's Public Hospital HREC in Melbourne. This HREC participates in National Mutual Acceptance of ethics. This means that the review of this committee in Victoria may be acceptable to other HRECs. Acknowledgement from JCU has also been received. This Project will also seek ethics review from two other HRECs in the Northern Territory. These are the:

- Menzies School of Health Research HREC
- Central Australian HREC

As this project is to be run in Qld, Victoria and the NT, ethics review is required from all these jurisdictions.

The selection of project sites

The project will invite ACCHSs in geographically diverse settings in Vic, Qld, and NT. Up to 22 ACCHSs will be able to participate. ACCHSs need to meet certain eligibility criteria to participate as project sites.

What is the pharmacist's role in the ACCHS?

The pharmacist employed within the ACCHS will deliver medication advice and education to patients and staff. They will work to improve patient medication adherence, improve prescribing, tailor medications to best suit the patient in collaboration with the prescriber, and assist with/oversee

medication management processes. They may provide health promotion, disease prevention, and assist patients with chronic disease self- management and more judicious use of medicines.

As a core role, the pharmacist will be required to respond to medication enquiries from patients and health professionals such as general practitioners and Aboriginal and Torres Strait Islander Health Workers/Practitioners, conduct staff education, review prescribing, mentor new prescribers, participate in case conferences, liaise across health sectors, undertake medication management reviews, and evaluate drug utilisation to ensure optimal therapy. As part of their collaborative work, an important element of the practice pharmacist's role is liaison with local community pharmacists to ensure continuity of care, and assist in medication management with transitions of care (such as when the patient is discharged from hospital).

These roles make up 10 core roles targeted *towards patients, and health professionals and health systems*. These roles are all non-dispensing, for which practice pharmacists are registered to deliver. This is summarised in Table 1.

Whilst the project has developed these core roles which form the foundation for the evaluation, each participating ACCHS has the flexibility to utilise the services of the pharmacist according to service and client priorities at the local level. Practice pharmacists will be supported to adapt to cultural ways of delivering primary health care within each service. Each ACCHS will be different and reflect the unique ways of providing culturally appropriate healthcare. This provides a pragmatic evaluation opportunity to document the diversity in pharmacist core roles and in the patient journey. This will be possible through qualitative evaluation, but also through pre-post Health Systems Assessments (this is explained later in this document). The practice pharmacist will be supported to adapt to their role as directed by the staff and CEO.

Most of the practice pharmacist's activity must be devoted to providing supportive clinical care to patients who are participants in this project.

Table 1. Summary of practice pharmacists core roles

SUMMARY OF PRACTICE PHARMACISTS CORE ROLES

Core Role #	Theme	Core activity
1 (a)	Medication Management Reviews	Pharmacist reviews the medication the patient is taking. The pharmacist initiates and facilitates a medication management review- which may be a Home Medicines Review (HMR) or a non-HMR (medication management review not conducted in the patient's home)
1 (b)		Pharmacist reviews the patient who had a HMR after 12 months and a Non-HMR after 3-6 months.
1 (c)		Pharmacist ensures the MMR is claimed by the practice when completed (as a DMMR item 900 or RMMR item 903)
2	Team-based collaboration	Pharmacist participates in clinic activities that support team-based chronic disease care plans, and cardiovascular (CV) risk assessment
3 (a)	Medication adherence assessment & support	Pharmacist assesses the medication adherence of the patient being seen
3 (b)		Pharmacist improves the patient's experience with their medicines
4	Medication appropriateness audit	Pharmacist assesses 'medication appropriateness and underutilisation of medicines' <u>as an audit of a sample</u> of patients with chronic disease.
5	Preventative health care	Pharmacist provides preventive interventions to patients
6	Drug Utilisation Review	Pharmacist conducts a DUR to audit and improve a priority issue at the service
7	Education and training	Pharmacist conducts education sessions at the service

8	Medicines information service	Pharmacist provides medicines related information to staff within the service and responds to clinician medicines enquiries.
9	Medicines stakeholder liaison	Pharmacist develops a written <u>stakeholder liaison plan</u> supporting engagement with community pharmacies.
10	Transitional care	Pharmacist facilitates care coordination with relevant hospitals; residential aged care facilities, etc.

Pharmacist's qualifications

Pharmacists who will be able to work in ACCHSs will be required to have:

- current registration with the Australian Health Practitioners Regulation Agency (AHPRA) as a pharmacist;
- more than 2 years post-registration experience;
- medication review accreditation such as from the Australia Association of Consultant Pharmacy (AACP) or Society of Hospital Pharmacists of Australia (SHPA) or working towards accreditation;
- post-graduate clinical qualifications or demonstrated clinical experience (e.g. hospital or HMRs).

The need for post-graduate qualifications or accreditation will be dependent on ACCHSs preference regarding the applicant and an adequate supply of accredited and experienced pharmacist applicants.

The PSA confirms that the proposed activities are consistent with the existing scope of practice of pharmacists as defined by the PSA Competency Standards endorsed by the Australian Health Practitioner Registration Agency.

Training the pharmacist at the ACCHS

The PSA will deliver the training to practice pharmacists in partnership with NACCHO. Some of the training will be off-site (before the pharmacist starts) and some will be on-site (at the start of their placement in the ACCHS). The NACCHO Coordinator and PSA training facilitator will arrange a training time with the practice pharmacist and with the nominated ACCHS, so that on-site training can best suit the ACCHS.

Some of the training that will be necessary for the practice pharmacist includes:

- locally appropriate cultural safety training,
- training on the ACCHS model of care,
- use of the CIS and other software used by ACCHSs,
- introduction to the Pharmacists log-book software,
- how to measure medication adherence and MAI (medication appropriateness),
- processes for recording of information,
- how to explain the pharmacists roles to patients and how to obtain patient consent,
- how to develop a work plan to undertake core roles,
- confidentiality in the clinic setting, teamwork processes, and delivering disease-specific services.

To follow up training, pharmacists will also have access to structured pharmacist mentor program that will link them with a dedicated mentor pharmacist with experience in the ACCH sector and to the other practice pharmacists within the project.

What patients are eligible to be participants in this project?

If the patient is aged 18 years of age and over and has the following conditions, then they are eligible to be a participant in this project:

- Cardiovascular disease (coronary heart disease, stroke, hypertension, dyslipidaemia and any other CV disease)
- Type 2 diabetes mellitus,
- Chronic kidney disease,
- Other chronic conditions that mean a patient is at high risk of developing medication-related problems (e.g. polypharmacy).

These conditions are selected because most of the mortality gap for Aboriginal and Torres Strait Islanders is due to these chronic diseases. Optimizing medicines for people with these conditions can make an important impact on their health.

The consent of the patient will be required to participate in this project. Most of the patients attending ACCHSs are of Aboriginal and Torres Strait Islander origin (81%).⁴ Therefore, most of the patients involved in this project will be of Aboriginal and Torres Strait Islander origin.

Patients who are regular patients of the service should be prioritised as pharmacists will make sure they follow-up these patients over time.

If a patient consents to be a participant, how may they benefit from this project?

These participants will have immediate access to an on-site pharmacist at no charge. The Pharmacist will check their medicines and make sure they are right for them. Some recommendations may require the prescriber to change medicines or their dose, or cease a medication, or start a necessary medication.

The pharmacist will help resolve problems the participant may have with taking medicines, storing them, and will assess for adverse effects. Participants will be offered medication review in the clinic, or at home, or a place that best suits them. Just like the doctors and other staff, the pharmacist will record the encounter and recommendations in the CIS so that the doctor and health team can read them and make any agreed prescribing changes. The pharmacist also has more time to spend on supporting participants with medications than the doctor has.

The Pharmacist will see participants again to provide them with ongoing support. The pharmacist may follow-up with other members of the primary healthcare team, including with community pharmacy, and depending on the participants needs, with the hospital for discharge medications. This intensive support may help to improve the health of the participant.

There are no other expectations on participants in this project. Personal details of participants are not collected at all, and the data being extracted for the project is completely de-identified. A *Participant Consent Form* and *Participant Information Brief* is available for the ACCHS and practice pharmacist to seek patient consent. Patient participation in this project is voluntary. If consent is not given, this will not affect the patient's routine treatment, or their relationship the clinic, and the patient will still be able to be referred to the Pharmacist.

If a patient consents to be a participant, how may this benefit the ACCHS?

If patients agree to be participants, this enables the ACCHS to collect information for the purpose of the project. The participation of the patient will assist the ACCHS to collect information to determine the clinical and cost-effectiveness of the practice pharmacist, and will support the clinic activity overall (with Medicare and staff education). The information will inform on whether the health of participants improves over time, compared to their health before they received the services of the pharmacist. The ACCHS may receive a site-specific report if they wish. If patient consent is not given, information cannot be extracted from the CIS for this project. Patient consent is therefore vital to assess the value of the practice pharmacist within ACCHSs.

How will patients be referred to the pharmacist in the ACCHS?

The staff within the ACCHS will need to be briefed about this project and the role of the practice pharmacist. This *Site Participation Brief* can assist the ACCHS with this task.

Patients attending the ACCHSs doctor, health worker or other healthcare provider will be invited to talk to a practice pharmacist. These staff can refer the patient to the practice pharmacist. NACCHO and the PSA will prepare some simple promotional material to help health staff with this referral, so that patients who are most in need and meet the inclusion criteria are offered the services of the pharmacist.

The practice pharmacist or a designated staff member will tell the patient about this Project (and provide the patient with the *participant information brief*) and ask them if they want to take part. They will then be asked to *sign a participant consent form*. They may see the Pharmacist straight away or an appointment may need to be made for a later time.

The practice pharmacists (with assistance from trained ACCHS staff) may also directly approach patients attending the clinic who meet the individual participant criteria. The process for participant recruitment will be flexible according to the preferred process recommended by the ACCHS. This can be arranged during the first site visit to the ACCHS (see later in this document).

How will our ACCHS seek patient consent?

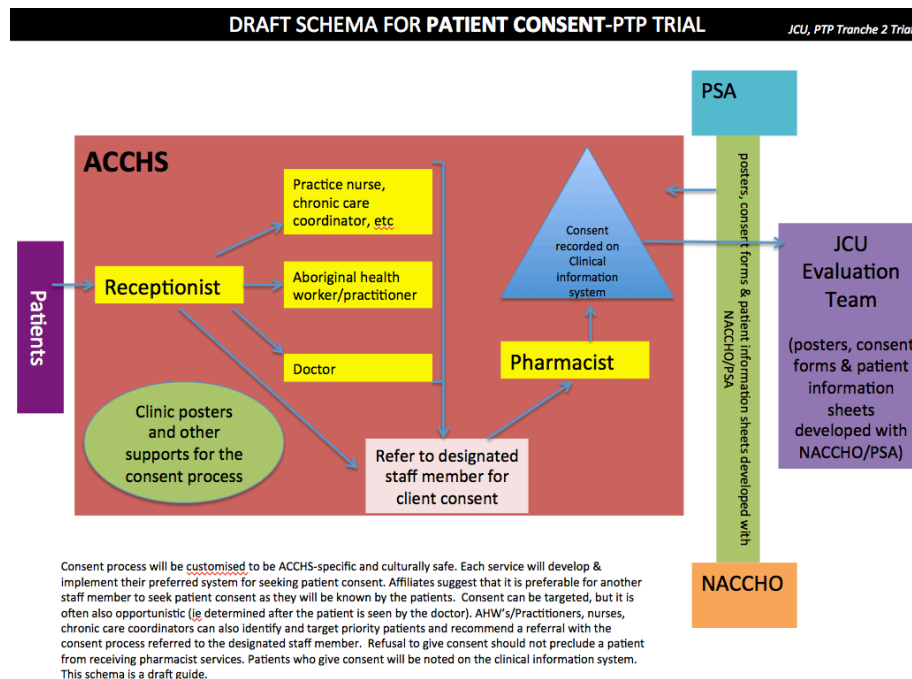
A suggested process for seeking individual patient consent has been developed in consultation with NACCHO Affiliates on the Evaluation Team. The process respects the systems that ACCHSs may wish and choose to adopt.

The practice pharmacist will be trained to seek the participant's consent. Training for seeking participant consent will also be provided to other staff who may be designated by the ACCHS to seek the participant's consent for cultural appropriateness reasons.

The participants consent form will then be signed and dated by the patient, a witness, and the designated staff member seeking patient consent. The consent form will be stored in a locked briefcase by the practice pharmacist until posted by registered post. It may be transmitted electronically to JCU after scanning. A written copy of the verbal information will be provided to the patient, including advice on how they may ask questions or make complaints about the project.

Consent will then be recorded on the clinical information system (CIS) by the practice pharmacist and GRHANITE will extract information only from consented patients. This suggested process is summarised in Figure 4.

Figure 4. A suggested process to seek patient consent.



How will participants be followed-up?

Practice Pharmacists will aim to follow-up participants using the usual clinic processes. Pharmacists will work with the existing staff in the ACCHS to follow-up participants in the same way used for all patients. Participants will need to be reviewed according to clinical needs and Medicare rules, and may include 3-monthly, 6-monthly or an annual review or more frequent review by the pharmacist.

The pharmacist will need to use the CIS within the ACCHS to record follow-up clinical details like other healthcare staff. The pharmacist will also record follow-up details in the pharmacist log-book as is appropriate for the type of review being conducted (such as medication appropriateness index measurements).

How many patients will ACCHS be asking to participate?

It is estimated that the practice pharmacist and the ACCHS may seek consent from about 350 people to be part of this Project and to see the Pharmacist over 15 months. This may vary considerably from service to service. It is important for the ACCHS to encourage patients to be referred to the pharmacist early in the project. This is so that enough time is available to follow-up patients during the 15 months the pharmacist is employed in the project.

Are there any risks or benefits to patients from taking part?

The Pharmacist is a qualified and registered health professional who will be trained to work in this ACCHS. The risks to patients are no different to seeing a Pharmacist in a Pharmacy, except that patients will be seeing Pharmacists in this clinic. The Pharmacists will not be prescribing or dispensing medicines as they would in a Pharmacy. They will be working with the primary health care team in the ACCHS.

How will information for the project be collected?

The project has been designed to be acceptable and feasible to ACCHSs and practice pharmacists, by making most of the data collection a 'by-product' of service delivery. There are three main types of information that will be collected with the help of ACCHSs. Information will be collected from clinical

information systems (CIS), pharmacist log-books (managed by the pharmacist), and from site visits to ACCHSs.

1. Deidentified information about patients who have consented (participants) will be collected from services clinical information systems (CIS), using an electronic data extraction tool known as **GRHANITE™**. ACCHSs will be supported to have the GRHANITE data extraction software installed in one personal computer in the clinic. This software will be installed in one workstation to minimise practice impact. When GRHANITE runs, it does so at a scheduled time and queries data from the practice database server. This is the only time GRHANITE communicates with the practice server. GRHANITE will extract weekly data from the CIS to the secure JCU repository. The ACCHS does not need to do anything to maintain that this program is working.

2. Practice pharmacists will also collect information about what they do through an **electronic log-book**. This system will be an online secure database requiring practice pharmacist secure log-in. It will be used by practice pharmacists to record deidentified daily activity. Each electronic log-book entry will be able to be interrogated by the JCU data custodian. The daily-recorded activity will refer to 6 core pharmacists' roles. The electronic interface will be user-friendly to minimise the reporting burden of practice pharmacists.

3. **Health systems assessment, qualitative data, and cost-effectiveness analysis** data will be collected during visits to the ACCHS. Mainly the NACCHO Project Coordinator, will undertake visits to the ACCHS. A qualitative researcher will visit only three ACCHSs if they are invited by the service. The costs related to the employment of pharmacists will be sourced mainly from the PSA.

What type of information will be collected by GRHANITE?

The information will be deidentified and only from consented patients (participants). The information will refer to periods 12 months before, and the periods after the pharmacist first provided support to the participants. This is summarised in Table 2.

Table 2. Deidentified patient information that will be extracted from clinical information systems (CIS) in the ACCHS

Measure	Detail
Patient characteristics	age, year of birth, sex, height and weight (for BMI), condition (diabetes, hypertension, dyslipidaemia, CHD, PAD, CVA, CKD, plus other disease (<i>in patients who fit the inclusion criteria with polypharmacy</i>), smoking status (history details: start/stop year), postcode, CTG status, ethnicity, Aboriginal and Torres Strait Islander status, DVA status, pension/concessional status, year of death.
Encounter/contact indices & other demographic measures	contacts with staff (different job roles), episodes of care (date of visit, reason for visit, duration, visit type), patient status/record status (active), created and updated dates and user who created and updated the record; consented patients; patients ID/MRN/UR number/chart No/record No
Biometric indices	Diastolic and systolic BP, HbA1c, lipids (HDL, LDL, TG's, and TC), CV absolute risk assessment (levels and risk), ACR, e-GFR,
Prescribing indices	All medications (including PBS drug code); all information contained within prescriptions (route, strength, formulation, quantity); date of the script being generated, including ceased/delete date; deleted flag (if any) and reason for delete or ceased; created and updated dates, and user (job role) who

created and updated the record. This information is for both current medications and past medications.

Dispensing indices

All medications (including PBS drug code); all information contained within prescriptions (route, strength, formulation, quantity); date of the medicine being supplied and dispensed; user (job role) who created and updated the record. This information is for both current medications and past medications.

Measures of health service utilisation:

Medicare Benefits Schedule indices

900 (DMMR or HMR), 903 (residential aged care DMMR or HMR), 721 (GPMP), 732 (GPMP review 3 months later), 715 (Health Check) and other MBS items related to the evaluation of pharmacist activities; record status, created and updated dates, and user (job role) who created and updated the record, item billing amount.

Non-HMR data (out-of home interviews)

non-HMR flagged in CIS will link this to the above variables (*to be recorded by the pharmacist*).

Measures of medication adherence

- Electronic measures of medication adherence (*to be calculated by the evaluators*)
- Medication Adherence (*to be recorded by the pharmacist*)

ACR= albumin-creatinine ratio; BP= blood pressure; CIS= clinical information systems; CKD= chronic kidney disease; CTG= Close The Gap; CV= cardiovascular; CVA= cerebrovascular disease; DET= data extraction tool (GRHANITE); DMMR= Domiciliary Medication Management Review; DVA: Dept of Veterans Affairs; e-GFR= electronic glomerular filtration rate; GPMP= General Practice Management Plan; HDL= high density lipoprotein; HMR= Home Medications Review; LDL= low density lipoprotein; MAI= Medication Appropriateness Index; PAD= peripheral artery disease; TC= total cholesterol; TG= triglyceride

What type of information will be collected by the pharmacist in the log-book?

The pharmacist will record their daily activity in the log-book. This will include information about education sessions they provided to staff, adhoc advice provided and any evidence this led to an outcome, the development of any resources for patients or the ACCHS, whether the pharmacist developed a plan to liaise with community pharmacy (and details of that plan), and the number of medicines reconciliations from stakeholders like hospitals.

In particular, the pharmacists log-book will enable practice pharmacists to record the results of the measurement of the 'medication appropriateness index' (MAI) and to assess for underutilisation of medicines (if necessary medicines are missing) for each of 30 participants.

A MAI is a more detailed and comprehensive assessment of the appropriateness of a patient's medication. Of the participants seen by a practice pharmacist, 30 participants per site will have their medications intensively appraised as part of the medication management review. The MAI will be measured in the first three months of the intervention phase (baseline) and recorded in the pharmacist's logbook. These audited participants will have their MAI assessed again 12 months later (within the implementation phase).

No personal information about participants is contained in the log-book. The participant does not need to be present as it is an audit of the participants medications held in the CIS.

The pharmacist will only report the unique 'patient ID' to enable matching of the medication appropriateness index audit of 30 participants to the participant data extracted through GHRANITE.

It is expected that the practice pharmacist will communicate the findings of the MAI and underutilization of medicines to the prescribing team within the ACCHS for each participant so that

appropriate clinical action is taken. Practice pharmacists will ensure that the MAI assessment takes account of additional clinical information such as an assessment of the participant's absolute cardiovascular risk when assessing their medications.

Practice Pharmacists will follow-up participants as per usual clinic processes. These follow-up mechanisms may vary from service to service (see above).

What type of information will be collected during the site visits?

Every participating ACCHS site will be visited at least twice during the project.

1. The 'needs assessment' visit (see *'what will happen during the first visit'*).
2. To conduct a 'health systems assessment' (HSA):
 - at the time of, or just prior to the appointment of the pharmacist, and
 - repeated towards the end of the implementation phase (month 12-15).

The NACCHO Project Coordinator will conduct visits and assessment with assistance from Affiliate staff. The needs assessment and health systems assessment will be conducted at the first visit.

The needs assessment will collect information about what the ACCHS may need to support the practice pharmacist to work in that clinic. This will be used to help the pharmacist to get started.

The 'health systems assessment' will source information about the ACCHS. Each ACCHS is different in many ways. The project needs to understand how many staff (and types) are employed within the ACCHS, the total service population, the total service budget, Aboriginal governance structures, health services on offer, CQI processes, models of care such as outreach, if home medicines reviews are conducted and how, type of CIS used, recall systems in place, the adequacy of existing communication with the hospital, and community pharmacy/ies, medicines access information, use of point of care testing, regional services available such as specialist and allied health visits, and how the ACCHS will implement and define the core roles of practice pharmacists.

A meeting with key informant staff in a focus group setting will be needed. This information will be collated in a summary report for the ACCHS to use for any quality assurance activity.

What type of information will be collected for qualitative analysis?

Three ACCHSs will be invited to participate in a qualitative evaluation of the Project in mid-late 2019. ACCHSs will be asked if they would support focus group discussions with certain patients, Aboriginal health workers/practitioners, and with the pharmacist on site. These meetings will be fully catered and will be conducted in ways to minimize clinic disruption. ACCHSs will be contacted closer to that time to explain what that might involve.

What will happen during the first visit to the ACCHS?

The 'needs assessment' visit to the ACCHS will elicit the type of support needed by the ACCHS so that the practice pharmacist may best be integrated within the service. The visit will also assist the ACCHS to establish their preferred system to seek patient consent, and ensure the pharmacist can use the CIS, has a space to consult with patients, and the CIS is set to accept the 'job-role' for the pharmacist (this is necessary for the GRHANITE data extraction). A 'health systems assessment' may also be undertaken at this visit (see above).

The NACCHO Project Coordinator will make contact at this visit with the nominated ACCHS staff member who will act as a 'go to' person. Together with the nominated 'go to' person/s and relevant ACCHS staff, a project consent pathway and process that is responsive to the local ACCHS' model of care will be planned. A second 'go to' person may also need to be identified by the ACCHS and Coordinator as contingency for leave, resignation or movement between clinics or roles.

A template poster for the ACCHS clinic will be provided by NACCHO. The NACCHO Project Coordinator will ensure that the service has adequate promotional material and strategies to engage both ACCHS staff and clients.

Use of information collected by the Project

The information collected from this project will be used to prepare reports to the Australian Government on 'quality of care' outcomes (the project objective) that arise from integrating a practice pharmacist within ACCHSs. The reports will assess change in the:

- quality of prescribing,
- quality of medicines support through indicators of health service utilization,
- quality of the patient, service and stakeholder experience, and
- ultimately an effect of these improvements on biometric indices as a measure of health outcome.

The reports will also assess the cost-effectiveness of the practice pharmacist within ACCHSs.

The data analysis will also be able to provide ACCHSs and Affiliates with local level and aggregated data. Most analyses at this level would not be meaningful because the number of participants will be too small. However, the information will be aggregated at a national level for the NACCHO, Affiliates, ACCHSs, and the PSA, as well as the Australian Government. This will inform the development of health policy about practice pharmacists and the role they can play supporting Aboriginal and Torres Strait Islander peoples with chronic disease in Australian primary health care settings.

Health systems assessment summaries will also be able to be provided to ACCHSs for their use.

Security of information collected by the Project

As the leading research organisation, JCU (the repository body) will be responsible for the protection of data from loss, misuse and unauthorised access. The Data Custodian (Biostatistician: Erik Biro) will be responsible for this role.

Further, the Project Operational Team, Chaired by the Deputy CEO of NACCHO, will be consulted in all matters brought to its attention with regard to concerns about data security.

How will the collected information be transported to JCU?

Completed Site Consent Forms will be collected by the NACCHO Project Coordinator, scanned and sent electronically to the data custodian. Participant consent forms will be scanned by the practice pharmacist and electronically transmitted to the data custodian. The forms will be stored electronically in a secure computer under the management of the data custodian on the property of College of Medicine and Dentistry, James Cook University.

Information extracted using GRHANITE and from the Pharmacist log-book will be transmitted electronically and stored on password-protected internal server on JCU premises. Data accessed during the analysis phase will be stored in JCU-supported database applications only.

Health Systems Assessment (HSA) and Needs Assessment information collected from site visits, will be collected on paper-based forms, (or in electronic format) collected by the NACCHO Project Coordinator and will be transported in a locked briefcase, scanned and stored in electronic format in a secure computer under the management of the data custodian.

Where and for how long is the information going to be kept?

Data will be kept for a minimum period of 7 years from the end of the year of publication of the last refereed publication or other form of public release to an audience external to JCU.

Electronic data will be stored on password-secured databases only. Any paper-based documents will be scanned and stored electronically, and the paper documents stored in a locked cabinet in a secure room at JCU. The data custodian (Biostatistician- Erik Biro) will be responsible for data storage consistent with the JCU *Code for the Responsible Conduct of Research*.

After the minimum period of storage, the data may be considered for disposal if there is a written request to the Evaluation Lead, from both the NACCHO and the PSA for the disposal of the data. As the raw unanalyzed data extracted by GRHANITE is owned by the ACCHSs, JCU will seek instruction from NACCHO and each ACCHS as to the ongoing use or destruction of this data. The Evaluation Lead will authorize the data custodian to delete the data if this is instructed by NACCHO, in accordance with the JCU *Code*.

Who will be able to access this information?

Data will be accessible only to members of the Evaluation Team who will have a role in handling this information. From time to time, one member of the evaluation team (the University of Melbourne HaBIC Research Information Technology Unit) may need access to the data-landing server at JCU to provide technical support services.

ACCHSs may request access to de-identified information from their service. These requests can be made to the Project Operational Team or its members, or directly through the NACCHO Affiliate or Project Officers involved in this project. The request must also include documentation of intended data use and must align with project objectives (the individual consent provided by each participant). Requests to access the data that *does not align* with the project objectives will need HREC approval. Similarly, Affiliates may request access to data at their jurisdictional level. This request must be in writing and align with the project objectives.

External requests from other organizations and research agencies not participating in this project to access data from this project will need to be submitted to the Project Operational Team. NACCHO will recommend that external agencies seek approval from Affiliates and from participating ACCHSs relevant to the request. Approval will not be granted for the release of data if it is not approved by NACCHO. There may be a need to seek approval from the Department of Health if this is a condition in the Head Agreement for this project. All external requests will need to have HREC approval prior to the release of this data.

What can we do if we have concerns about data security, research misconduct or complaints?

ACCHSs can report any breaches in data security or research misconduct or complaints to:

- project partners/staff,
- Affiliates,
- NACCHO directly, and/or
- Designated HREC representative.

Reports received by project staff will be forwarded to the Project Operational Team and the Deputy CEO of NACCHO.

Who can GPs contact for more information or to make a complaint?

GPs can contact the NACCHO Project Lead: Mike Stephens, Tel: 02 6246 9300; Email: mike.stephens@naccho.org.au. Other Project staff to contact include: Deb Bowden from the Pharmaceutical Society of Australia: Tel: 02 6283 4740; Email: Deb.Bowden@psa.org.au. You can also contact the NACCHO Deputy Chief Executive Officer: Ms Dawn Casey at dawn.casey@naccho.org.au.

The Human Research Ethics Committees will continue to provide oversight as the project progresses. You can contact the Ethics Committee with any concerns about the safety and fairness of the Project

at: Executive Office of Research, St Vincent's Hospital Melbourne, Tel: 03 9231 2394, or email:
research.ethics@svhm.org.au

Thank you on behalf of the IPAC Project Team.

The **IPAC Project** is the *Integrating Pharmacists within ACCHSs to improve Chronic Disease Management Project (IPAC)*. The Project Partners and Project Operational Team for the **IPAC Project** include: The National Aboriginal Community Controlled Health Organisation (NACCHO); Pharmaceutical Society of Australia, and the College of Medicine and Dentistry, James Cook University. **Evaluation Team** members include the Project Partners, and the Victorian Aboriginal Community Controlled Health Organisation (VACCHO); Queensland Aboriginal and Islander Health Council (QAIHC); and the Aboriginal Medical Services Alliance in the NT (AMSANT). The Project Reference Group includes representatives of NACCHO, Affiliates and ACCHSs.

¹ Pharmaceutical Society of Australia. *Guide to providing pharmacy services to Aboriginal and Torres Strait Islander people*. Jul 2014.

<http://www.psa.org.au/download/guidelines/Guide-to-providing-pharmacy-services-to-Aboriginal-and-Torres-Strait-Islander-people.pdf>

² Couzos S, Murray R: Health, Human Rights and the Policy Process. In: *Aboriginal Primary Health Care: An Evidence-based Approach*. edn. Edited by Couzos S, Murray R. Melbourne: Oxford University Press; 2007: 29-63.

³ Tan ECK, Stewart K, Elliott RA, George J. Integration of pharmacists into general practice clinics in Australia: the views of general practitioners and pharmacists. *Int J Pharm Pract* 2014;22(1):28–37. At: <http://onlinelibrary.wiley.com/doi/10.1111/ijpp.12047/pdf>

MASTER GENERAL PRACTITIONER CONSENT FORM



Name of Project: *Integrating Pharmacists within Aboriginal Community Controlled Health Services to improve Chronic Disease Management (IPAC) Project*

Name of Aboriginal Community Controlled Health Organisation: insert name of ACCHS

Project Leaders: Ms Dawn Casey, Mr Mike Stephens (NACCHO), Associate Professor Sophia Couzos (JCU), Ms Deb Bowden (PSA)

Evaluation Organisation: Evaluation Team led by the College of Medicine and Dentistry, JCU.

Project Sponsor: James Cook University (JCU)

1. The purpose of the Project, as outlined in the attached General Practitioner Participation Brief, has been explained, and I have had the opportunity to ask questions about the project.
2. I have the right to withdraw my consent and cease any further involvement in this Project at any time in accordance with my employment contract.
3. I will support the Practice Pharmacist to utilise the information contained within the clinical information system to undertake their clinical duties, and support the data collection required for this Project.
4. I will support the recording of de-identified participant data from consenting patients in the clinical information system.
5. I will participate in on-site support visits to assist our service to integrate the Practice Pharmacist role into our health service team
6. I will participate in on-site visits and telephone interviews if required to facilitate data collection about our health service.
7. I will support the ACCHS staff to obtain the written consent of individual participants in this Project.
8. I understand that if I have any complaints or questions concerning this Project I can contact any of the key contacts mentioned in the General Practitioner Participation Brief. This includes the St Vincent's Hospital Melbourne, Human Research Ethics Committee with contact details as follows: Executive Office of Research, St Vincent's Hospital Melbourne, Tel: 03 9231 2394, or email: research.ethics@svhm.org.au
9. I understand I will receive a signed copy of this document and the General Practitioner Participation Brief to keep.

(General Practitioner)

(Signature of General Practitioner)

(Date)

(Witness)

(Signature of Witness)

(Date)

(Team member)

(Signature of Team member)

(Date)

The **IPAC Project** is the *Integrating Pharmacists within ACCHSs to improve Chronic Disease Management Project (IPAC)*. The Project Partners and Project Operational Team for the **IPAC Project** include: The National Aboriginal Community Controlled Health Organisation (NACCHO); Pharmaceutical Society of Australia, and the College of Medicine and Dentistry, James Cook University. *Evaluation Team* members include the Project Partners, and the Victorian Aboriginal Community Controlled Health Organisation (VACCHO); Queensland Aboriginal and Islander Health Council (QAIHC); and the Aboriginal Medical Services Alliance in the NT (AMSANT). The Project Reference Group includes representatives of NACCHO, Affiliates and ACCHSs.

MASTER PHARMACIST PARTICIPATION BRIEF



Title	<i>Integrating Pharmacists within Aboriginal Community Controlled Health Service (ACCHSs) to improve Chronic Disease Management Project (IPAC)</i>
Short Title	<i>Putting Pharmacists into ACCHSs</i>
Project Sponsor	<i>James Cook University</i>
Coordinating Investigators	<i>Associate Professor Sophia Couzos (JCU), Ms Deb Bowden (PSA), Mr Mike Stephens (NACCHO), Ms Dawn Casey (NACCHO)</i>
Evaluation Team	<i>Prof Rhondra Jones (JCU), Dr Emily Callander (Griffith Uni), Dr Erik Biros (JCU), Dr Deborah Smith (JCU), Prof Bev Glass (JCU), Dr Robyn Preston (JCU), Ms Priscilla Page (JCU), Mr Donald Whaleboat (JCU), Assoc Prof Michelle Belling (JCU), Ms Nicole Bates (JCU), Mr Mark (Joseph) Thomas, Dr Nadia Lusi (VACCHO), Dr Elizabeth Moore (AMSANT), Mr Roderick Wright (QAIHC), Dr Katie Panaretto, Dr Douglas Boyle</i>
Location	<i>[Name of ACCHS]</i>

What is the IPAC Project?

IPAC stands for 'Integrating Pharmacists within Aboriginal Community Controlled Health Service (ACCHSs) to improve Chronic Disease Management' Project.

This project will explore if including a registered non-dispensing practice pharmacist as part of the primary health care team within Aboriginal community controlled health services (ACCHSs) leads to improvements in the quality of the care received by Aboriginal and Torres Strait Islander peoples. The project will explore improvements in prescribing by doctors, if patients are more likely to take their medicines, and if indicators of their health are improving over time, by measuring these factors before and after the pharmacist is appointed. Practice pharmacists will work with the doctors and other health staff in each ACCHS for a period of 15 months per service, in Vic, Qld and the NT.

Practice pharmacists will provide relevant healthcare activities within their scope of practice to patients. They will also provide education and training to existing staff within the services (as appropriate), improve relations with community pharmacies to overcome barriers that patients may face in accessing medicines, and assist in managing medications at transitions of care (such as discharge from hospital). This project will also explore the cost-effectiveness of pharmacist integration within ACCHSs.

How did this Project come about?

The Project was developed at the request of the National Aboriginal Community Controlled Health Organisation (NACCHO, representing ACCHSs across Australia) and the Pharmaceutical Society of Australia (PSA, representing pharmacists). The Project is a tripartite partnership between NACCHO, PSA and James Cook University (JCU). Participants include Affiliates of NACCHO in Vic, Qld, and the NT, up to 22 ACCHSs in these jurisdictions, practice pharmacists, and patients who will receive healthcare support from a pharmacist.

Community-based participatory research principles and methods are used to make sure there is appropriate Aboriginal governance over this Project.

Why is this Project important?

Aboriginal and Torres Strait Islander peoples experience a much higher burden of chronic disease due to cardiovascular, diabetes, and other health problems, and yet have poorer access to needed medicines.¹² Adverse health outcomes from these illnesses are preventable

if prescribing quality is improved, and patients are better supported with medicines use, which is a key health equity issue.

Non-dispensing pharmacists are not currently funded consistently or reliably to work within primary health care settings in the public health sector in Australia. Despite this, several ACCHSs across Australia have innovatively sourced funds and/or developed partnerships with community pharmacy's to source pharmacists in non-dispensing roles. This project is modelled on these pharmacists' roles and on international research evidence. There is extensive global evidence that practice pharmacists co-located within general practice clinics can enhance chronic disease management and quality use of medicines.³

The NACCHO and the PSA have promoted the need for this project for many years. The project will help the Australian Government make decisions about future funding and the role practice pharmacists may play as members of primary health care teams within ACCHSs and potentially other settings in Australia.

What is the aim of this project?

This project aims to improve quality of care outcomes for Aboriginal and/or Torres Strait Islander adult patients with chronic disease by integrating a practice pharmacist within the primary health care team of ACCHSs. This means the Project will investigate:

- Improvements in health measures of those patients who have been receiving support from a pharmacist and who agree to participate in the Project;
- Improvements in:
 - prescribing so that medicines patients are taking are appropriate for them and their individual healthcare needs;
 - patient adherence to medicines;
 - health service utilisation of Medicare;
 - relationships with and perceptions of stakeholders (ACCHSs staff; community pharmacies; pharmacists);
- The cost-effectiveness of the intervention, which will investigate the costs of the pharmacist service and measures of effectiveness such as increased Medicare utilisation (as a marker of increased patient access to healthcare services towards equity).

Does this project have ethics approval?

Ethics approval has been received from a Victorian Human Research Ethics Committee (HREC). This is the St Vincent's Public Hospital HREC in Melbourne. This HREC participates in National Mutual Acceptance of ethics. This means that the review of this committee in Victoria may be acceptable to other HRECs. Acknowledgement from JCU has also been received. This Project will also seek ethics review from two other HRECs in the Northern Territory. These are the:

- Menzies School of Health Research HREC
- Central Australian HREC

As this project is to be run in Qld, Victoria and the NT, ethics review is required from all these jurisdictions.

How is the Project funded?

The Australian Government under the Pharmacy Trials Program of the 6th Community Pharmacy Agreement has funded the project for 29 months.

Governance

The Project Partners and the Project Operational Team

This project is a partnership between the PSA, NACCHO, and JCU (College of Medicine and Dentistry), guided by a Memorandum of Understanding that outlines communication and governance processes.

The PSA, as the lead agency, is responsible for managing the Head Agreement with the Department of Health, and service agreements with partners and ACCHSs, and will coordinate the appointment of practice pharmacists, their recruitment, selection, placement, and training. The NACCHO will provide Aboriginal governance leadership for the project and coordinate all communication with ACCHSs, Affiliates and the NACCHO Board. JCU will undertake the project evaluation, having developed the research methodology based around a pragmatic, community-based participatory research model.

The Project Operational Team is made up of the project partners and is Chaired by the Deputy CEO of NACCHO, Ms Dawn Casey.

Steering Committee

The Project Operational Team will report to this group as this is made up of representatives of the Project partners, the Department of Health, the Pharmacy Guild of Australia and external experts.

Members of the Evaluation Team

The Project Partners are members of the evaluation team as are other Aboriginal community representative bodies. These are the Victorian Aboriginal Community Controlled Health Organisation (VACCHO); the Queensland Aboriginal and Islander Health Council (QAIHC), and the Aboriginal Medical Services Alliance in the NT (AMSANT). These organisations are NACCHO Affiliates and will be responsible for state-based service support to registered ACCHSs, and provide guidance to the project as members of the evaluation team.

Project Reference Group

State and Territory Affiliates of NACCHO (QAIHC, VACCHO and AMSANT) will be members of the Project Reference Group. Participating ACCHSs will also be invited to be members of the Project Reference Group managed by NACCHO. The Chair of the Project Reference Group will be a nominated member of the NACCHO Board of Directors. This group will meet by teleconference or web-based platforms.

Aboriginal governance and leadership

The way in which these groups communicate and link with each other is shown in Figure 1 and 2. The Project respects and acknowledges Aboriginal governance principles, and ACCHS sector leadership and involvement.

Figure 1. Governance and partnership structure of the IPAC project

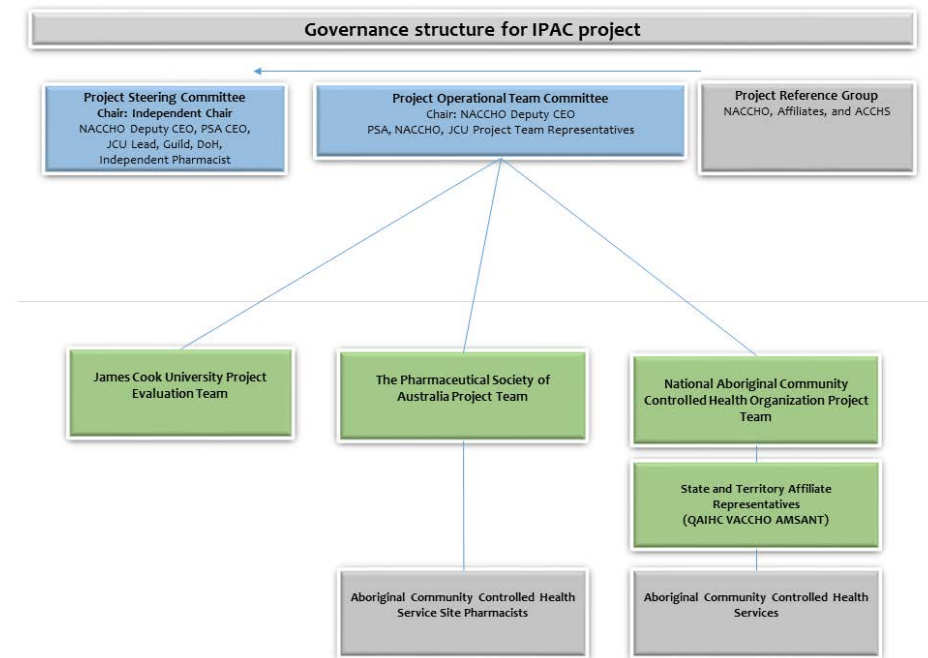
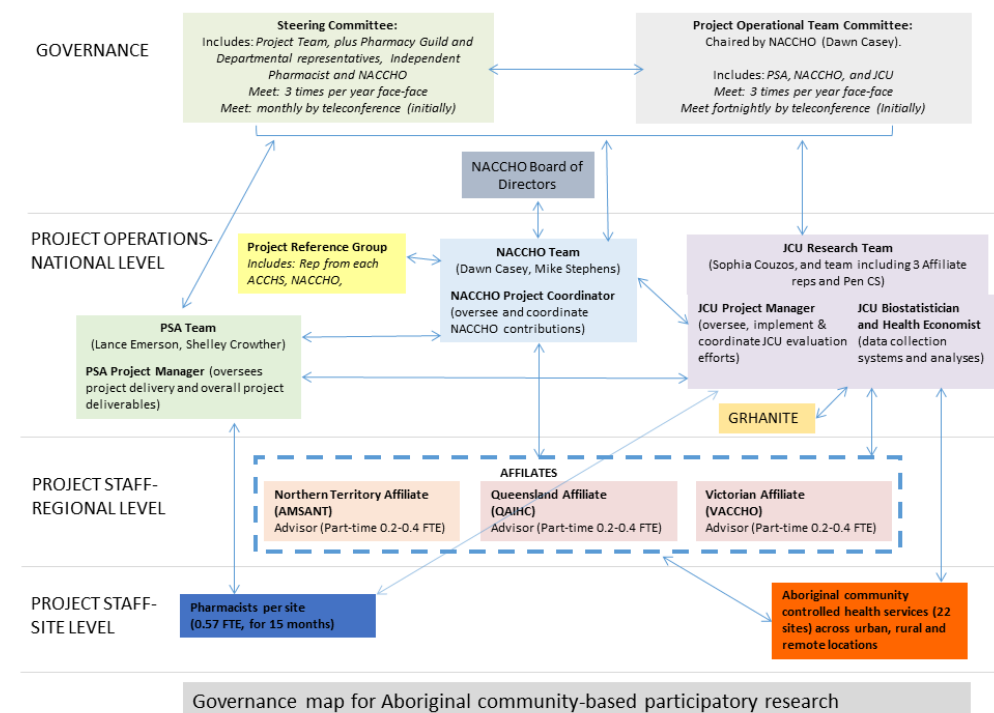


Figure 2. Governance map for the IPAC project.



What is the design of this project?

The project partners are committed to undertaking the Project to ensure clear benefits to ACCHSs, and to ensure acceptability and sustainability of the intervention within ACCHSs.

The project is a pre and post study where the pharmacist intervention will be added to standard primary health care practice within ACCHSs. Information will be collected from the time the pharmacist starts until they finish, and this will be compared with information from 12 months before the pharmacist started.

The parts of the project

There are three project phases over a 29 month project duration: Phase 1: Establishment (4 months); Phase 2: Implementation/intervention (19 months); Phase 3: Analysis and Reporting (6 months). The project is scheduled to be completed by April 2020. ACCHSs will be invited in stages (tranches) and will therefore be staggered. This is so that the project can give time to each service to get them ready for the project.

The selection of project sites

The project is inviting ACCHSs in geographically diverse settings in Vic, Qld, and NT. Up to 22 ACCHSs will be able to participate. ACCHSs need to meet certain eligibility criteria to participate as project sites.

The eligibility criteria for ACCHSs is:

- The ACCHS employs at least one (1) full-time- equivalent (FTE) general practitioner per clinic who is able to prescribe medicines to clients of that organisation.
- The ACCHS does not currently employ a non-dispensing practice pharmacist at the participating clinic.
- The ACCHS uses a clinical information system such as Communicare, Best Practice, and Medical Director.
- The ACCHS has participated in continuing quality improvement and reporting on the national Key Performance Indicators for at least 24 months through the use of electronic data extraction tools.
- The ACCHS is participating in the *Quality Assurance for Aboriginal and Torres Strait Islander Medical Services* (QAAMS) program, if it is conducting 'point of care' testing.
- The ACCHS agrees to download the GRHANITE data extraction tool into one computer within the practice, adhere to program business rules/protocol and guidelines, data provision requirements, and patient/service consent requirements for the evaluation of the program.
- The ACCHS can provide the practice pharmacist access to a private consulting room on the clinic premises that has access to the clinical information system used by the practice.
- The ACCHS can allocate a staff member who will act as a 'go to' person to assist the practice to obtain informed patient consent.
- The ACCHS is a member of NACCHO, and the relevant NACCHO State/Territory Affiliate.
- The ACCHS is an accredited practice in accordance with the RACGP Practice Standards.
- In non-remote locations, the ACCHS must be participating or eligible to participate in the PBS co-payment measure (practice incentive program).
- In remote locations, the ACCHS must be eligible to participate in the remote Section 100 arrangements for the supply of pharmaceutical benefits

These criteria have been developed with Affiliate input to suit most ACCHSs in Qld, Vic, and the NT, and to make the project as 'real life' as possible. It is important that ACCHSs have clinical information systems (CIS) that the pharmacist can use like other health staff. Only the listed clinical information systems can work with the GRHANITE™ tool to collect information. (GRHANITE is explained later in this document).

The project will recognise the diversity of Aboriginal peoples and Torres Strait Islanders and models of care across Australia, and will select ACCHSs in urban, regional and remote areas. This is so that the project can understand the many ways that ACCHSs may utilise the pharmacist in their clinic.

How will ACCHSs be invited to take part?

ACCHSs will be invited to participate in the project by NACCHO and Affiliates through an 'expression of interest' process. The 'expression of interest' process will explain to ACCHS the process that will be used for site selection.

The Project Operational Team, Chaired by the NACCHO Deputy CEO will review the expressions of interest and decide if a temporary Panel made up of Affiliate representatives is necessary to select the most suitable sites to participate in the project. As the recruitment process for sites will be staggered, this process will be repeated.

When NACCHO receives an expression of interest from an ACCHS, and the ACCHS is agreed to being a suitable site, the NACCHO Project Coordinator will contact the ACCHS and explain the project further to provide instructions on the process required to establish the site participation.

Formal participation of ACCHSs

After this consultation, a Site Agreement, Site Consent form, and Site Participation Brief (*this document*) will be provided to the ACCHS. Once this is signed and agreed, the project officers will arrange for practice pharmacist recruitment and placement within the ACCHS.

A visit to the ACCHS will be arranged to undertake a 'Needs Assessment' and a 'Health Systems Assessment' just before, or at the time that the practice pharmacist commences (these are explained later in this document).

How will each ACCHS benefit from this project?

Each service will be offered a practice pharmacist (aggregated 0.57 FTE across 22 sites each for 15 months duration) under a service agreement with the PSA. This will enhance the medicines-related workforce capacity of the ACCHS. Practice pharmacists are registered to work within their scope of practice and will have a non-dispensing role. The appointments will include salary, training, and the provision of supportive resources.

In the short-term, Medicare claims for medications-related, preventive care and chronic disease care may increase. The practice pharmacist will support other staff with quality prescribing and medicines use. The relationship with community pharmacies in the local area may improve if pharmacies' are helped to provide more appropriate services to the local community. Relationships between the ACCHS, local hospitals and other care providers may improve with communication between care providers when it pertains to the medicines that patients are taking.

These short-term benefits have potential for long-term gains for the sector as a whole. The project will provide the Australian Government with the evidence-base (biomedical, process, and economic evaluations) for the development of national health policies to potentially support on-going resourcing for practice pharmacists integrated within ACCHSs.

What is the role of the Affiliates in this Project?

NACCHO is a project partner and will maintain Aboriginal governance over this project. Affiliates are also participants in this project. They will be providing support to ACCHSs through funded project officer positions (0.2-0.4 FTE). The ACCHS will be notified of the name and contact details of the Affiliate staff to contact if and when the service needs to.

What is the pharmacist's role in the ACCHS?

The pharmacist employed within the ACCHS will deliver medication advice and education to patients and staff. They will work to improve patient medication adherence, improve prescribing, tailor medications to best suit the patient in collaboration with the prescriber, and assist with/oversee medication management processes. They may provide health promotion, disease prevention, and assist patients with chronic disease self-management and more judicious use of medicines.

The pharmacist will be required to respond to medication enquiries from patients and health professionals such as general practitioners and Aboriginal and Torres Strait Islander Health Workers/Practitioners, conduct staff education, review prescribing, mentor new prescribers, participate in case conferences, liaise across health sectors, undertake medication management reviews, and evaluate drug utilisation to ensure optimal therapy. As part of their collaborative work, an important element of the practice pharmacist's role is liaison with local community pharmacists to ensure continuity of care, and assist in medication management with transitions of care (such as when the patient is discharged from hospital).

Overall, there are 10 core roles targeting *patients*, and *health professionals and health systems*. These roles are all non-dispensing, for which practice pharmacists are registered to deliver. This is summarised in Table 1.

Whilst the project has developed these core roles for evaluation purposes, each participating ACCHS has the flexibility to utilise the services of the pharmacist according to service and client priorities. Practice pharmacists will be supported to adapt to cultural ways of delivering primary health care within each service. The project will aim to document the diversity in pharmacist core roles and in the patient journey. This will be possible through qualitative evaluation, but also through pre-post Health Systems Assessments (this is explained later in this document). The practice pharmacist will be supported to adapt to their role as directed by the staff and CEO.

Most of the practice pharmacist's activity must be devoted to providing supportive clinical care to patients who are participants in this project.

Table 1. Summary of practice pharmacists core roles

SUMMARY OF PRACTICE PHARMACISTS CORE ROLES		
Core Role #	Theme	Core activity
1 (a)	Medication Management Reviews	Pharmacist reviews the medication the patient is taking. The pharmacist initiates and facilitates a medication management review- which may be a Home Medicines Review (HMR) or a non-HMR (medication management review not conducted in the patient's home)
1 (b)		Pharmacist reviews the patient who had a HMR after 12 months and a Non-HMR after 3-6 months.
1 (c)		Pharmacist ensures the MMR is claimed by the practice when completed (as a DMMR item 900 or RMMR item 903)
2	Team-based collaboration	Pharmacist participates in clinic activities that support team-based chronic disease care plans, and cardiovascular (CV) risk assessment
3 (a)	Medication adherence assessment & support	Pharmacist assesses the medication adherence of the patient being seen
3 (b)		Pharmacist improves the patient's experience with their medicines
4	Medication appropriateness audit	Pharmacist assesses 'medication appropriateness and underutilisation of medicines' <u>as an audit of a sample</u> of patients with chronic disease.

5	Preventative health care	Pharmacist provides preventive interventions to patients
6	Drug Utilisation Review	Pharmacist conducts a DUR to audit and improve a priority issue at the service
7	Education and training	Pharmacist conducts education sessions at the service
8	Medicines information service	Pharmacist provides medicines related information to staff within the service and responds to clinician medicines enquiries.
9	Medicines stakeholder liaison	Pharmacist develops a written <u>stakeholder liaison plan</u> supporting engagement with community pharmacies.
10	Transitional care	Pharmacist facilitates care coordination with relevant hospitals; residential aged care facilities, etc.

Pharmacist's qualifications

Pharmacists who will be able to work in ACCHSs will be required to have:

- current registration with the Australian Health Practitioners Regulation Agency (AHPRA) as a pharmacist;
- more than 2 years post-registration experience;
- medication review accreditation such as from the Australia Association of Consultant Pharmacy (AACP) or Society of Hospital Pharmacists of Australia (SHPA) or working towards accreditation;
- post-graduate clinical qualifications or demonstrated clinical experience (e.g. hospital or HMRs).

The need for post-graduate qualifications or accreditation will be dependent on ACCHSs preference regarding the applicant and an adequate supply of accredited and experienced pharmacist applicants.

The PSA confirms that the proposed activities are consistent with the existing scope of practice of pharmacists as defined by the PSA Competency Standards endorsed by the Australian Health Practitioner Registration Agency.

Training the pharmacist at the ACCHS

The PSA will deliver the training to practice pharmacists in partnership with NACCHO. Some of the training will be off-site (before the pharmacist starts) and some will be on-site (at the start of their placement in the ACCHS). The NACCHO Coordinator and PSA training facilitator will arrange a training time with the practice pharmacist and with the nominated ACCHS, so that on-site training can best suit the ACCHS.

To follow up training, pharmacists will also have access to structured pharmacist mentor program that will link them with a dedicated mentor pharmacist with experience in the ACCH sector and to the other practice pharmacists within the project.

What patients' are eligible to be participants in this project?

If the patient is aged 18 years of age and over and has the following conditions, then they are eligible to be a participant in this project:

- Cardiovascular disease (coronary heart disease, stroke, hypertension, dyslipidaemia and any other CV disease)
- Type 2 diabetes mellitus,
- Chronic kidney disease,
- Other chronic conditions that mean a patient is at high risk of developing medication-related problems (e.g. polypharmacy).

These conditions are selected because *most* of the mortality gap for Aboriginal and Torres Strait Islanders is due to these chronic diseases. Optimizing medicines for people with these conditions can make an important impact on their health.

The consent of the patient will be required to participate in this project. Most of the patients attending ACCHSs are of Aboriginal and Torres Strait Islander origin (81%).⁴ Therefore, we expect most of the patients involved in this project will be of Aboriginal and Torres Strait Islander origin.

Patients who are regular patients of the service should be prioritised as pharmacists will make sure they follow-up these patients over time.

If a patient consents to be a participant, how may they benefit from this project?

These participants will have immediate access to an on-site pharmacist at no charge. The Pharmacist will check their medicines and make sure they are right for them. Some recommendations may require the prescriber to change medicines or their dose, or cease a medication, or start a necessary medication.

The pharmacist will help resolve problems the participant may have with taking medicines, storing them, and will assess for adverse effects. Participants will be offered medication review in the clinic, or at home, or a place that best suits them. Just like the doctors and other staff, the pharmacist will record the encounter and recommendations in the CIS so that the doctor and health team can read them and make any agreed prescribing changes. The pharmacist also has more time to spend on supporting participants with medications than the doctor has.

The Pharmacist will see participants again to provide them with ongoing support. The pharmacist may follow-up with other members of the primary healthcare team, including with community pharmacy, and depending on the participants needs, with the hospital for discharge medications. This intensive support may help to improve the health of the participant.

There are no other expectations on participants in this project. Personal details of participants are not collected at all, and the data being extracted for the project is completely de-identified. A *Participant Consent Form* and *Participant Information Brief* is available for the ACCHS and practice pharmacist to seek patient consent. Patient participation in this project is voluntary. If consent is not given, this will not affect the patient's routine treatment, or their relationship the clinic, and the patient will still be able to be referred to the Pharmacist.

If a patient consents to be a participant, how may this benefit the ACCHS?

If patients agree to be participants, this enables the ACCHS to collect information for the purpose of the project. The participation of the patient will assist the ACCHS to collect information to determine the clinical and cost-effectiveness of the practice pharmacist, and will support the clinic activity overall (with Medicare and staff education). The information will inform on whether the health of participants improves over time, compared to their health before they received the services of the pharmacist. The ACCHS may receive a site-specific report if they wish. If patient consent is not given, information cannot be extracted from the CIS for this project. Patient consent is therefore vital to assess the value of the practice pharmacist within ACCHSs.

How will patients be referred to the pharmacist in the ACCHS?

The staff within the ACCHS will need to be briefed about this project and the role of the practice pharmacist. The project will also seek the consent of general practitioners in the clinic

and provide them with an *information brief*. This *Site Participation Brief* can assist the ACCHS with informing other staff.

Patients attending the ACCHSs doctor, health worker or other healthcare provider will be invited to talk to a practice pharmacist. These staff can refer the patient to the practice pharmacist. NACCHO and the PSA will prepare some simple promotional material to help health staff with this referral, so that patients who are most in need and meet the inclusion criteria are offered the services of the pharmacist.

The practice pharmacist or a designated staff member will tell the patient about this Project (and provide the patient with the *participant information brief*) and ask them if they want to take part. They will then be asked to *sign a participant consent form*. They may see the Pharmacist straight away or an appointment may need to be made for a later time.

The practice pharmacists (with assistance from trained ACCHS staff) may also directly approach patients attending the clinic who meet the individual participant criteria. The process for participant recruitment will be flexible according to the preferred process recommended by the ACCHS. This can be arranged during the first site visit to the ACCHS (see later in this document).

How will our ACCHS seek patient consent?

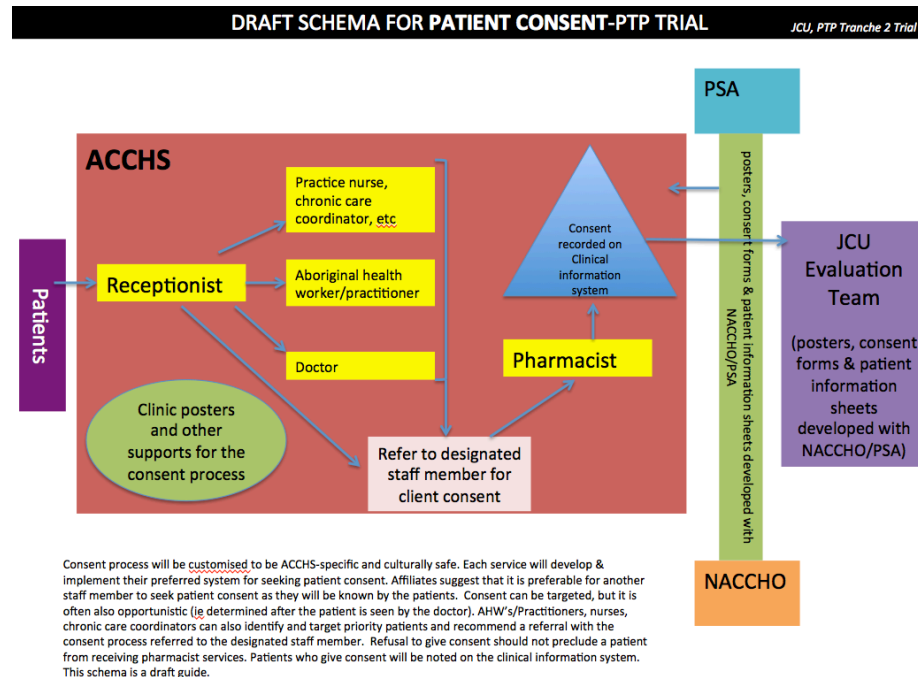
A suggested process for seeking individual patient consent has been developed in consultation with NACCHO Affiliates on the Evaluation Team. The process respects the systems that ACCHSs may wish and choose to adopt.

The practice pharmacist will be trained to seek the participant's consent. Training for seeking participant consent will also be provided to other staff who may be designated by the ACCHS to seek the participant's consent for cultural appropriateness reasons.

The participants consent form will then be signed and dated by the patient, a witness, and the designated staff member seeking patient consent. The consent form will be stored in a locked briefcase by the practice pharmacist until posted by registered post. It may be transmitted electronically to JCU after scanning. A written copy of the verbal information will be provided to the patient, including advice on how they may ask questions or make complaints about the project.

Consent will then be recorded on the clinical information system (CIS) by the practice pharmacist and GRHANITE will extract information only from consented patients. This suggested process is summarised in Figure 4.

Figure 4. A suggested process to seek patient consent.



How will participants be followed-up?

Practice Pharmacists will aim to follow-up participants using the usual clinic processes. Pharmacists will work with the existing staff in the ACCHS to follow-up participants in the same way used for all patients. Participants will need to be reviewed according to clinical needs and Medicare rules, and may include 3-monthly, 6-monthly or an annual review or more frequent review by the pharmacist.

The pharmacist will need to use the CIS within the ACCHS to record follow-up clinical details like other healthcare staff. The pharmacist will also record follow-up details in the pharmacist log-book as is appropriate for the type of review being conducted (such as medication appropriateness index measurements).

How many patients will ACCHS be asking to participate?

It is estimated that the practice pharmacist and the ACCHS may seek consent from about 350 people to be part of this Project and to see the Pharmacist over 15 months. This may vary considerably from service to service.

It is important for the ACCHS to encourage patients to be referred to the pharmacist early in the project. This is so that enough time is available to follow-up patients during the 15 months the pharmacist is employed in the project.

Are there any risks or benefits to patients from taking part?

The Pharmacist is a qualified and registered health professional who will be trained to work in this ACCHS. The risks to patients are no different to seeing a Pharmacist in a Pharmacy, except that patients will be seeing Pharmacists in this clinic. The Pharmacists will not be prescribing or dispensing medicines as they would in a Pharmacy. They will be working with the primary health care team in the ACCHS.

How will information for the project be collected?

The project has been designed to be acceptable and feasible to ACCHSs and practice pharmacists, by making most of the data collection a 'by-product' of service delivery. There

are three main types of information that will be collected with the help of ACCHSs. Information will be collected from clinical information systems (CIS), pharmacist log-books (managed by the pharmacist), and from site visits to ACCHSs.

1. Deidentified information about patients who have consented (participants) will be collected from services clinical information systems (CIS), using an electronic data extraction tool known as **GRHANITE™**. ACCHSs will be supported to have the GRHANITE data extraction software installed in one personal computer in the clinic. This software will be installed in one workstation to minimise practice impact. When GRHANITE runs, it does so at a scheduled time and queries data from the practice database server. This is the only time GRHANITE communicates with the practice server. GRHANITE will extract weekly data from the CIS to the secure JCU repository. The ACCHS does not need to do anything to maintain that this program is working.
2. Practice pharmacists will also collect information about what they do through an **electronic log-book**. This system will be an online secure database requiring practice pharmacist secure log-in. It will be used by practice pharmacists to record deidentified daily activity. Each electronic log-book entry will be able to be interrogated by the JCU data custodian. The daily-recorded activity will refer to 6 core pharmacists' roles. The electronic interface will be user-friendly to minimise the reporting burden of practice pharmacists.
3. **Health systems assessment, qualitative data, and cost-effectiveness analysis** data will be collected during visits to the ACCHS. Mainly the NACCHO Project Coordinator, will undertake visits to the ACCHS. A qualitative researcher will visit only three ACCHSs if they are invited by the service. The costs related to the employment of pharmacists will be sourced mainly from the PSA.

How does GRHANITE work and how secure is it?

GRHANITE™ strictly conforms to extract only data that is approved. It provides ethical and secure mechanisms for the provision of data from the CIS. If an individual gives their permission to be involved in a project, GRHANITE can read this consent information if it is recorded in the clinical notes. Patients who have not consented will not have their data interrogated, even if deidentified. This is an 'opt-in' consent process. Patient names, dates of birth, address or other identifying information are not extracted.

The data extraction from the CIS within the ACCHS will only extract deidentified data and then transmit it securely to the secure repository at JCU. The exported data is encrypted, and can only be decrypted at its final destination. This ensures transmission security. Data is deidentified as patients are assigned a unique patient ID. It is not possible for the project partners to reidentify any patient.

GRHANITE software will not operate if copied or moved from one computer to another. All installations require a unique authorising license. It is a nationally recognised tool as over 1000 health services across Australia have used/are using this for quality improvement and for research activity.

JCU will be the repository body responsible for the protection of data from loss, misuse and unauthorised access. A data custodian will be appointed (the biostatistician investigator). JCU will comply with the Code for the Responsible Conduct of Research (JCU) [This Code has been adapted from the Australian Code for the Responsible Conduct of Research ["the National Code"], developed jointly by the National Health and Medical Research Council, Australian Research Council and Universities Australia, and published in 2007.⁵

What type of information will be collected by GRHANITE?

The information will be deidentified and only from consented patients (participants). The information will refer to periods 12 months before, and the periods after the pharmacist first provided support to the participants. This is summarised in Table 2.

Table 2. Deidentified patient information that will be extracted from clinical information systems (CIS) in the ACCHS

Measure	Detail
Patient characteristics	age, year of birth, sex, height and weight (for BMI), condition (diabetes, hypertension, dyslipidaemia, CHD, PAD, CVA, CKD, plus other disease (<i>in patients who fit the inclusion criteria with polypharmacy</i>), smoking status (history details: start/stop year), postcode, CTG status, ethnicity, Aboriginal and Torres Strait Islander status, DVA status, pension/concessional status, year of death.
Encounter/contact indices & other demographic measures	contacts with staff (different job roles), episodes of care (date of visit, reason for visit, duration, visit type), patient status/record status (active), created and updated dates and user who created and updated the record; consented patients; patients ID/MRN/UR number/chart No/record No
Biometric indices	Diastolic and systolic BP, HbA1c, lipids (HDL, LDL, TG's, and TC), CV absolute risk assessment (levels and risk), ACR, e-GFR,
Prescribing indices	All medications (including PBS drug code); all information contained within prescriptions (route, strength, formulation, quantity); date of the script being generated, including ceased/delete date; deleted flag (if any) and reason for delete or ceased; created and updated dates, and user (job role) who created and updated the record. This information is for both current medications and past medications.
Dispensing indices	All medications (including PBS drug code); all information contained within prescriptions (route, strength, formulation, quantity); date of the medicine being supplied and dispensed; user (job role) who created and updated the record. This information is for both current medications and past medications.
Measures of health service utilisation:	
Medicare Benefits Schedule indices	900 (DMMR or HMR), 903 (residential aged care DMMR or HMR), 721 (GPMP), 732 (GPMP review 3 months later), 715 (Health Check) and other MBS items related to the evaluation of pharmacist activities; record status, created and updated dates, and user (job role) who created and updated the record, item billing amount.
Non-HMR data (out-of home interviews)	non-HMR flagged in CIS will link this to the above variables (<i>to be recorded by the pharmacist</i>).
Measures of medication adherence	<ul style="list-style-type: none"> Electronic measures of medication adherence (<i>to be calculated by the evaluators</i>) Medication Adherence (<i>to be recorded by the pharmacist</i>)

ACR= albumin-creatinine ratio; BP= blood pressure; CIS= clinical information systems; CKD= chronic kidney disease; CTG= Close The Gap; CV= cardiovascular; CVA= cerebrovascular disease; DET= data extraction tool (GRHANITE); DMMR= Domiciliary Medication Management Review; DVA= Dept of Veterans Affairs; e-GFR= electronic glomerular filtration rate; GPMP= General Practice Management Plan; HDL= high density lipoprotein; HMR= Home Medications Review; LDL= low density lipoprotein; MAI= Medication Appropriateness Index; PAD= peripheral artery disease; TC= total cholesterol; TG= triglyceride

What type of information will be collected by the pharmacist in the log-book?

The pharmacist will record their daily activity in the log-book. This will include information about education sessions they provided to staff, adhoc advice provided and any evidence this led to an outcome, the development of any resources for patients or the ACCHS, whether the pharmacist developed a plan to liaise with community pharmacy (and details of that plan), and the number of medicines reconciliations from stakeholders like hospitals.

In particular, the pharmacists' log-book will enable practice pharmacists to record the results of medication assessments for each of 30 participants. Of the participants seen by a practice pharmacist, 30 participants per site will have their medications intensively appraised as part of the medication management review.

No personal information about participants is contained in the log-book. The participant does not need to be present for the medication assessment as it is an audit of the participants medications held in the CIS.

The pharmacist will only record the unique 'patient ID' to enable matching of the medication assessment audit of 30 participants to the participant data extracted through GRHANITE.

The practice pharmacist will communicate the findings of the medication assessment for the participant to the prescribing team within the ACCHS so that appropriate clinical action is taken. Practice pharmacists will ensure that the assessment takes account of additional clinical information such as an assessment of the participant's absolute cardiovascular risk when assessing their medications.

Practice Pharmacists will follow-up participants as per usual clinic processes. These follow-up mechanisms may vary from service to service (see above).

What type of information will be collected during the site visits?

Every participating ACCHS site will be visited at least twice during the project.

1. The 'needs assessment' visit (see *'what will happen during the first visit'*).
2. To conduct a 'health systems assessment' (HSA):
 - at the time of, or just prior to the appointment of the pharmacist, and
 - repeated towards the end of the implementation phase (month 12-15).

The NACCHO Project Coordinator will conduct visits and assessment with assistance from Affiliate staff. The needs assessment and health systems assessment will be conducted at the first visit.

The *'needs assessment'* will collect information about what the ACCHS may need to support the practice pharmacist to work in that clinic. This will be used to help the pharmacist to get started.

The *'health systems assessment'* will source information about the ACCHS. Each ACCHS is different in many ways. The project needs to understand how many staff (and types) are employed within the ACCHS, the total service population, the total service budget, Aboriginal governance structures, health services on offer, quality improvement processes, models of care such as outreach, if home medicines reviews are conducted and how, type of CIS used, recall systems in place, the adequacy of existing communication with the hospital, and community pharmacy/ies, medicines access information, use of point of care testing, regional services available such as specialist and allied health visits, and how the ACCHS will implement and define the core roles of practice pharmacists.

A meeting with key informant staff in a focus group setting will be needed to undertake the health systems assessment. This information will be collated in a summary report for the ACCHS to use for any quality assurance activity.

What type of information will be collected for qualitative analysis?

Three ACCHSs will be invited to participate in a qualitative evaluation of the Project in mid-late 2019. ACCHSs will be asked if they will support focus group discussions with certain patients, Aboriginal health workers/practitioners, and with the pharmacist on site. These meetings will be fully catered and will be conducted in ways to minimize clinic disruption. ACCHSs will be contacted closer to that time to explain what that might involve.

What will happen during the first visit to the ACCHS?

The 'needs assessment' visit to the ACCHS will elicit the type of support needed by the ACCHS so that the practice pharmacist may best be integrated within the service. The visit will also assist the ACCHS to establish their preferred system to seek patient consent, and ensure the pharmacist can use the CIS, has a space to consult with patients, and the CIS is set to accept the 'job-role' for the pharmacist (this is necessary for the GRHANITE data extraction). A 'health systems assessment' may also be undertaken at this visit (see above).

The NACCHO Project Coordinator will make contact at this visit with the nominated ACCHS staff member who will act as a 'go to' person. Together with the nominated 'go to' person/s and relevant ACCHS staff, a project consent pathway and process that is responsive to the local ACCHS' model of care will be planned. A second 'go to' person may also need to be identified by the ACCHS and Coordinator as contingency for leave, resignation or movement between clinics or roles.

The NACCHO Project Coordinator will ensure that the service has adequate promotional material and strategies to engage both ACCHS staff and clients.

Who owns the GRHANITE information?

The raw (unanalysed) data collected from the GRHANITE data extraction is owned by the ACCHS even though it will be used, analysed and stored safely by JCU. Details regarding this is included in the service agreement with the ACCHS for this project.

Intellectual Property

Details regarding Intellectual Property of the Project will be included in the Service Agreement with the PSA.

Use of information collected by the Project

The information collected from this project will be used to prepare reports to the Australian Government on 'quality of care' outcomes (the project objective) that arise from integrating a practice pharmacist within ACCHSs. The reports will assess change in the:

- quality of prescribing,
- quality of medicines support through indicators of health service utilization,
- quality of the patient, service and stakeholder experience, and
- ultimately an effect of these improvements on biometric indices as a measure of health outcome.

The reports will also assess the cost-effectiveness of the practice pharmacist within ACCHSs.

The data analysis will also be able to provide ACCHSs and Affiliates with local level and aggregated data. Most analyses at this level would not be meaningful because the number of

participants will be too small. However, the information will be aggregated at a national level for the NACCHO, Affiliates, ACCHSs, and the PSA, as well as the Australian Government. This will inform the development of health policy about practice pharmacists and the role they can play supporting Aboriginal and Torres Strait Islander peoples with chronic disease in Australian primary health care settings.

Health systems assessment summaries will also be able to be provided to ACCHSs for their use.

Security of information collected by the Project

As the leading research organisation, JCU (the repository body) will be responsible for the protection of data from loss, misuse and unauthorised access. The Data Custodian (Biostatistician: Erik Biros) will be responsible for this role.

Further, the Project Operational Team, Chaired by the Deputy CEO of NACCHO, will be consulted in all matters brought to its attention with regard to concerns about data security.

How will the collected information be transported to JCU?

Completed Site Consent Forms will be collected by the NACCHO Project Coordinator, scanned and sent electronically to the data custodian. Participant consent forms will be scanned by the practice pharmacist and electronically transmitted to the data custodian. The forms will be stored electronically in a secure computer under the management of the data custodian on the property of College of Medicine and Dentistry, James Cook University.

Information extracted using GRHANITE and from the Pharmacist log-book will be transmitted electronically and stored on password-protected internal server on JCU premises. Data accessed during the analysis phase will be stored in JCU-supported database applications only.

Health Systems Assessment (HSA) and Needs Assessment information collected from site visits, will be collected on paper-based forms, (or in electronic format) collected by the NACCHO Project Coordinator and will be transported in a locked briefcase, scanned and stored in electronic format in a secure computer under the management of the data custodian.

Where and for how long is the information going to be kept?

Data will be kept for a minimum period of 7 years from the end of the year of publication of the last refereed publication or other form of public release to an audience external to JCU.

Electronic data will be stored on password-secured databases only. Any paper-based documents will be scanned and stored electronically, and the paper documents stored in a locked cabinet in a secure room at JCU. The data custodian (Biostatistician- Erik Biros) will be responsible for data storage consistent with the JCU *Code for the Responsible Conduct of Research*.

After the minimum period of storage, the data may be considered for disposal if there is a written request to the Evaluation Lead, from both the NACCHO and the PSA for the disposal of the data. As the raw unanalyzed data extracted by GRHANITE is owned by the ACCHSs, JCU will seek instruction from NACCHO and each ACCHS as to the ongoing use or destruction of this data. The Evaluation Lead will authorize the data custodian to delete the data if this is instructed by NACCHO, in accordance with the JCU *Code*.

Who will be able to access this information?

Data will be accessible only to members of the Evaluation Team who will have a role in handling this information. From time to time, one member of the evaluation team (the University of Melbourne HaBIC Research Information Technology Unit) may need access to the data-landing server at JCU to provide technical support services.

ACCHSs may request access to de-identified information from their service. These requests can be made to the Project Operational Team or its members, or directly through the NACCHO Affiliate or Project Officers involved in this project. The request must also include documentation of intended data use and must align with project objectives (the individual consent provided by each participant). Requests to access the data that *does not align* with the project objectives will need HREC approval. Similarly, Affiliates may request access to data at their jurisdictional level. This request must be in writing and align with the project objectives.

External requests from other organizations and research agencies not participating in this project to access data from this project will need to be submitted to the Project Operational Team. NACCHO will recommend that external agencies seek approval from Affiliates and from participating ACCHSs relevant to the request. Approval will not be granted for the release of data if it is not approved by NACCHO. There may be a need to seek approval from the Department of Health if this is a condition in the Head Agreement for this project. All external requests will need to have HREC approval prior to the release of this data.

What can we do if we have concerns about data security, research misconduct or complaints?

ACCHSs can report any breaches in data security or research misconduct or complaints to:

- project partners/staff,
- Affiliates,
- NACCHO directly, and/or
- Designated HREC representative.

Reports received by project staff will be forwarded to the Project Operational Team and the Deputy CEO of NACCHO.

What is the role of ACCHSs in this project?

The ACCHS will host the practice pharmacist who will be providing health services to the patients in the community. The pharmacist will effectively be an employee of the PSA, who will provide all employment support. This will minimise the administrative burden on the ACCHS so that the pharmacist and ACCHS can focus on effective service delivery from the start. NACCHO and respective Affiliates will have the capacity to liaise closely with PSA, ACCHS and the pharmacist to ensure that the pharmacist's roles are understood clearly by both parties.

The Head Agreement between the PSA and the Department of Health will influence the service agreement between the PSA and the ACCHS. The Service Agreement with the ACCHS will document the terms of participation including: Health Service Responsibilities and Financial Arrangements.

ACCHSs will be provided with a *Site Consent Form* that will need to be signed if the ACCHS agrees to be a participant in this project.

The NACCHO Project Coordinator will be available to ACCHSs to assist in understanding and delivering on their roles within the project. They may also work with their Affiliate representative to assist ACCHSs.

The following is a summary of the ACCHSs role as a participant in this project that will be negotiated with each ACCHS to be most appropriate for that service. The role of the ACCHS is:

- To nominate a 'go to' person to be a point of contact for the project staff.
- To support the practice pharmacist to use the CIS within the practice, and access the patient's clinical records in order to support patient care and make medicines-related recommendations to other health staff.

- To enable the CIS to recognise the practice pharmacist in their 'job role'. (The ACCHS will be assisted with this. This is so that the information can be collected about the work the pharmacist has done).
- To support the pharmacist to access a private consulting room to meet with patients.
- To support the practice pharmacist to have time to record their work and findings in the pharmacist log-book.
- To assist the practice pharmacist to work with other members of the health care team by sharing information about the project with other members of the team.
- To assist the pharmacist to prepare a workplan that best suits the model of care of the ACCHS.
- To host information for patients attending the practice by using posters and other health promotion material to promote patients to be participants in this project.
- To develop a participant consent process that is approved by the ACCHS involving the practice pharmacist and/or other staff in the ACCHS.
- To support site visits and support a focus group with relevant staff for 'health systems assessment' and 'needs assessment'.
- To support site visits and support focus groups with relevant staff for the qualitative evaluation if the ACCHS wishes to volunteer as a case study site (further information about this will be provided to ACCHS to make a decision in 2019).
- Any other matters that are relevant to the work of the practice pharmacist that the ACCHS may wish to consider. (Examples include mechanisms for home medicines review, or use of point of care testing, etc).

What support will ACCHSs receive in this project?

Each ACCHS that participates in the project will receive:

- The services of an on-site registered practice pharmacist for a 15-month duration.
- Administration of pharmacist employment and contract to be provided by PSA.
- The opportunity to select their preferred practice pharmacist.
- A 'Needs Assessment' site visit to ascertain any specific needs of ACCHS.
- A facilitated 'training' on-site visit to support and prepare the practice pharmacist within the primary healthcare team.
- Resources to support the practice pharmacist, such as medication management guides.
- A supportive mentor for the practice pharmacist (that will be managed by NACCHO and the PSA).
- Installation of the GRHANITE data extraction tool in the CIS and licence for its use for 15 months.
- Two site visits to explore Health Systems Assessment (one of these will be at the same time as the needs assessment visit).
- A Health Systems Assessment Report for ACCHS use for CQI.
- Involvement of a nominated staff member to be a member of the Project Reference Group in the project.
- Support from a nominated Affiliate officer involved in this project.
- Support from the NACCHO Project Coordinator during site visits and contact by email and phone.
- An opportunity to review project findings and provide feedback through ACCHS membership of the Project Reference Group.
- Customised reports specific to the participating ACCHS (if requested and if the data analysis is meaningful due to limitations with small participant numbers).

Each Affiliate that participates in the project will receive:

- Remuneration to participate in the project. This can be used to employ a part-time project officer (or to back-fill existing staff).
- Involvement of nominated staff as members of the Evaluation Team in the project.
- An opportunity to review project findings and provide feedback (through membership of the evaluation team and Project reference group).
- Customised reports specific to the jurisdiction (if requested).

How will ACCHSs find out the results of the Project?

ACCHSs will receive information about the Project through NACCHO communication mechanisms. The Project will finish at ACCHSs in late 2019. The ACCHSs will know the results in 2020. Other ways in which ACCHSs will be informed include:

- Through the Project Reference Group which will be provided with updates on progress with the project and extracts of reports arising from the project.
- Summary results to individual ACCHSs (pertaining to their own data) may be provided upon request to the Project Operational Team, although these may not be meaningful due to small participant numbers and the inability to undertake data analysis.
- Extracts of reports arising from this project will be summarized in plain language and disseminated according to usual NACCHO communication mechanisms, such as email, the NACCHO News, and NACCHO website, including communication with any relevant special interest groups supported by NACCHO.
- Presentations detailing progress and results will be communicated at NACCHO and/or Affiliate Conferences and Annual Meetings.

The findings of the project will also be reported for publication in articles and journals relevant to this project. There may also be presentations at conferences.

Reports will also be provided to the Australian Government, Department of Health, and through communication mechanisms used by the Pharmaceutical Society of Australia. NACCHO (as a project partner) will check this information before it is released.

Can ACCHSs decide to withdraw from this project?

ACCHSs and Affiliates that are participants reserve the right to withdraw their participation in the project in accordance with their service agreements. If an ACCHS site withdraws, the ACCHS will be asked to provide a written reason for the withdrawal to the PSA (for the contract) and the Project Operational Team. The ACCHS will be asked whether they agree to the continued use of the data collected in this Project prior to their withdrawal of Site Consent. The withdrawal of the Site from the project will mean the withdrawal of the site support specified in the service agreement (and explained above). The withdrawal of the Site will be reported to all relevant HRECs when the Project's annual report is due.

Can Pharmacists decide to withdraw from this project?

Pharmacists participating reserve the right to withdraw their participation in the project in accordance with their employment contract.

Who can Pharmacists contact for more information or to make a complaint?

Pharmacists can contact Deb Bowden from the Pharmaceutical Society of Australia: Tel: 02 6283 4740; Email: Deb.Bowden@psa.org.au. Alternatively you can contact the NACCHO Project Lead: Mike Stephens, Tel: 02 6246 9300; Email: mike.stephens@naccho.org.au. Or the NACCHO Deputy Chief Executive Officer: Ms Dawn Casey at dawn.casey@naccho.org.au.

The Human Research Ethics Committees will continue to provide oversight as the project progresses. You can contact the Ethics Committee with any concerns about the safety and fairness of the Project at: Executive Office of Research, St Vincent's Hospital Melbourne, Tel: 03 9231 2394, or email: research.ethics@svhm.org.au

Thank you on behalf of the IPAC Project Team.

The **IPAC Project** is the *Integrating Pharmacists within ACCHSs to improve Chronic Disease Management Project (IPAC)*. The Project Partners and Project Operational Team for the **IPAC Project** include: The National Aboriginal Community Controlled Health Organisation (NACCHO); Pharmaceutical Society of Australia, and the College of Medicine and Dentistry, James Cook University. **Evaluation Team** members include the Project Partners, and the Victorian Aboriginal Community Controlled Health Organisation (VACCHO); Queensland Aboriginal and Islander Health Council (QAIHC); and the Aboriginal Medical Services Alliance in the NT (AMSANT). The Project Reference Group includes representatives of NACCHO, Affiliates and ACCHSs.

¹ Pharmaceutical Society of Australia. *Guide to providing pharmacy services to Aboriginal and Torres Strait Islander people*. Jul 2014. <http://www.psa.org.au/download/guidelines/Guide-to-providing-pharmacy-services-to-Aboriginal-and-Torres-Strait-Islander-people.pdf>

² Couzos S, Murray R: Health, Human Rights and the Policy Process. In: *Aboriginal Primary Health Care: An Evidence-based Approach*. edn. Edited by Couzos S, Murray R. Melbourne: Oxford University Press; 2007: 29-63.

³ Tan ECK, Stewart K, Elliott RA, George J. Integration of pharmacists into general practice clinics in Australia: the views of general practitioners and pharmacists. *Int J Pharm Pract* 2014;22(1):28–37. At: <http://onlinelibrary.wiley.com/doi/10.1111/ijpp.12047/pdf>

⁴ Australian Institute of Health and Welfare 2016. *Healthy Futures—Aboriginal Community Controlled Health Services: Report Card* 2016. Cat. no. IHW 171. Canberra: AIHW.

⁵ JCU Code for the Responsible Conduct of Research (JCU) <https://www.jcu.edu.au/policy/research-management/code-for-the-responsible-conduct-of-research>

MASTER PHARMACIST CONSENT FORM



Name of Project: *Integrating Pharmacists within Aboriginal Community Controlled Health Services to improve Chronic Disease Management (IPAC) Project*

Name of Aboriginal Community Controlled Health Organisation: insert name of ACCHS

Project Leaders: Ms Dawn Casey, Mr Mike Stephens (NACCHO), Associate Professor Sophia Couzos (JCU), Ms Deb Bowden (PSA)

Evaluation Organisation: Evaluation Team led by the College of Medicine and Dentistry, JCU.

Project Sponsor: James Cook University (JCU)

1. The purpose of the Project, as outlined in the attached Pharmacist Participation Brief, has been explained, and I have had the opportunity to ask questions about the project.
2. I have the right to withdraw my consent and cease any further involvement in this Project at any time in accordance with my employment contract.
3. As the Practice Pharmacist employed by the ACCHS, I will participate in off-site and on-site training as required, delivered by a visiting facilitator from the PSA in consultation with NACCHO.
4. I will have access to the clinical information system and will utilise the information contained within to undertake my clinical duties, and to support the data collection required for this Project.
5. I will record participant data from consenting patients in the clinical information system, and also record activity in a Pharmacist Log-book as outlined in the Pharmacist Participation Brief.
6. I will participate in on-site support visits to assist our service to integrate my role into our health service team
7. I will participate in on-site visits and telephone interviews to facilitate data collection about our health service.
8. I will receive assistance from the ACCHS staff to obtain the written consent of individual participants in this Project.
9. Project staff and partners will ensure there is continuing consultation with me during the course of this Project.
10. I understand that if I have any complaints or questions concerning this Project I can contact any of the key contacts mentioned in the Pharmacist Participation Brief. This includes the St Vincent's Hospital Melbourne Human Research Ethics Committee with contact details as follows: Executive Office of Research, St Vincent's Hospital Melbourne, Tel: 03 9231 2394, or email: research.ethics@svhm.org.au
11. I understand I will receive a signed copy of this document and the Pharmacist Participation Brief to keep.

(Pharmacist)

(Signature of Pharmacist)

(Date)

(Witness)

(Signature of Witness)

(Date)

(Team member)

(Signature of Team member)

(Date)

The **IPAC Project** is the *Integrating Pharmacists within ACCHSs to improve Chronic Disease Management Project (IPAC)*. The Project Partners and Project Operational Team for the **IPAC Project** include: The National Aboriginal Community Controlled Health Organisation (NACCHO); Pharmaceutical Society of Australia, and the College of Medicine and Dentistry, James Cook University. *Evaluation Team* members include the Project Partners, and the Victorian Aboriginal Community Controlled Health Organisation (VACCHO); Queensland Aboriginal and Islander Health Council (QAIHC); and the Aboriginal Medical Services Alliance in the NT (AMSANT). The Project Reference Group includes representatives of NACCHO, Affiliates and ACCHSs.