Updated By: [redacted]

Initial Approval Submission - New Project

***SAVE before ticking 'Complete' or closing the form. --- If Complete is ticked, un-tick it to edit form.

Human Research Ethics Committee

Initial Approval Submission - New Project

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

* **I confirm I am applying for Initial approval for a new research project where the UON HREC is the lead committee.**

* *Tick to continue*

HREA

* Have you already determined that you will have to complete the *Human Research Ethics Application* (HREA), i.e. your research has the potential for harm? ☐ Yes No

Protocol Identification

* Project T tle:

[redacted]

* Project summary:

Sports pharmacy is an emerging field that includes management and prevention of injury, and advice about medicines. Although sports-related injuries in primary care are often managed by physiotherapists, consumers can seek adv ce and purchase products and Over-The-Counter medicines from community pharmacists. This qual tative study will explore percept ons of pharmacists and physiotherapists in rural/remote and urban areas about current and potential roles in sports pharmacy, to provide insight into barriers to, and facilitators of, pharmacist input.
Max 6 lines

Duration of Project

Provide the ant cipated start and end dates for the whole of the project, including participant follow-up if appl cable and data analysis.

* Anticipated start date: [redacted] * Anticipated end date: [redacted]

* Are there any time-critical aspects relating to the research of wh ch the HREC should be aware? Yes No☐

Please describe the time-crit cal aspects.

The project will form part of [redacted] PhD thesis.

Research Personnel

Name:
[redacted]

CI / Supervisor
☐

Start Date
[redacted]

End Date

Role
Co-Inv

Certification: Office use only

Certification	Begin	End
	-	-

Name:
[redacted]

CI / Supervisor
☐

Start Date
[redacted]

End Date

Role
Student Researcher

Certification: Office use only

Certification	Begin	End
	-	-

Name:
[redacted]

CI / Supervisor

Start Date
[redacted]

End Date

Role
CI

Certification: Office use only

Certification	Begin	End
	-	-

Name:
[redacted]

CI / Supervisor
☐

Start Date
[redacted]

End Date

Role
Co-Inv

Certification: Office use only

Certification	Begin	End
	-	-

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Research Personnel Not Listed

* Were any members of the research team not listed in the personnel p cklist? ☐ Yes No

Student Researchers

* Was one or more people given the role of Student Researcher? Yes ☐ No

* Type of program student(s) undertaking? *(If more than one student, select the highest level.)* Postgraduate Research

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Project Funding/Support

Yes ☐ No * Is the research the subject of a contract / agreement / grant awarded from or under considerat on by an internal or external grants body, sponsor, etc?

Approval From Other HRECs

Yes ☐ No * Has the research been approved, or is under cons deration, by another Human Research Eth cs Comm ttee (HREC)?

* *Tick to continue*

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Type of Research

Does your project involve:

Yes ☐ No * Research to be conducted outside Australia involving participants NS4.8

Yes ☐ No * Research on workplace practices or possibly impacting on workplace relat onships

Yes ☐ No * Decept on or lim ted disclosure to part cipants NS2.3.1

Yes ☐ No * Access to existing data sets, databanks, or human tissue (including cell lines) NS3.2

Yes ☐ No * Collection or extraction of human tissue, blood or other body fluids NS3.4

Yes ☐ No * Access to **personally identifiable** information / records / human tissue samples without specif c consent from the individuals to whom the information/records relate NS2.3; NS2.3.6; NS3.4

Yes ☐ No * Human genetic testing / research NS3.5

Yes ☐ No * A cellular therapy

Yes ☐ No * Exposing participants to ionising radiat on NS2.1

Yes ☐ No * Clinical trial under the CTN or CTX scheme

Yes ☐ No * Use of gametes or use or creat on of embryos

Yes ☐ No * Use of drugs; alternative / complementary therapies or care; or surgical, or other therapeut c or diagnostic procedures and devices NS3.3

Yes ☐ No * An innovat on or intervention which is not standard practice in the study populat on NS3.3

Yes ☐ No * Other type of research not covered above
Note: You must tick **Yes** if you have answered 'No' to all of above

Research Population

The category and source of part cipants being sought for this research are:

Select **all that apply** even if there will not be direct contact with the participants.
You must **select at least one.**

- Adults 18 years of age or older
- ☐ Children, or young people under 18 years who are not University students NS4.2

- ☐ A focus on Aboriginal and Torres Strait Islander (ATSI) peoples, groups, communities or issues NS4.7
- ☐ A focus on women who are pregnant, and/or research involving the human foetus NS4.1
- ☐ A focus on people w th a cognitive impairment, an intellectual disability, or a mental illness NS4.5
- ☐ Adult part cipants who will not be competent to give consent are expected to be recruited NS2.2.12
- ☐ People highly dependent on med cal care who may be unable to give consent, eg unconsc ous or too ill NS4.4

- ☐ The general public

- Students or staff of the Univers ty of Newcastle
- Students or staff of other univers ties / colleges
- ☐ School children, ie recruited through schools

- ☐ Volunteer registers or databases
- ☐ Members of particular community groups/ organisations
- Employees of particular organisations
- ☐ Clients / patients of health service providers
- ☐ Hospital in-patients
- ☐ Clients of organisations / commun ty services
- ☐ Prisoners or those held in detention

- ☐ People who have a sight or hearing impairment
- ☐ People with a specif c health cond tion
- ☐ People in a dependent or unequal relationship w th the researchers
- ☐ Participants not proficient in the English language

- ☐ Records / information about people without contact with those people
- ☐ Human tissue collect ons without contact with the donors
- ☐ People who could be exposed to civil, criminal or other proceedings as a result of the research

- ☐ Other

Research Methods/Techniques

The research methods / techn ques to be used in the research are:

Select all that apply. You must **select at least one.**

- ☐ Computer based tests
- ☐ Data linkage
- ☐ Focus groups
- Interviews face-to-face
- Interviews telephone
- ☐ Internet / web based research
- ■ Observat on of people
- ☐ Covert observation NS2.3.1
- ☐ Photographs of people

- ☐ Physical activ ties / exercises / tests
- ☐ Psychological tests

- ☐ Quest onnaire / survey / diary anonymous
- ☐ Quest onnaire / survey / diary dentifying
- ☐ Record / document analysis
- Taping audio / video

- ☐ Access to and/or use of information from a Commonwealth Agency
- ☐ Access to and/or use of information from a private sector organisation

- ☐ Case study
- ☐ Case-control study
- ☐ Epidem olog cal or other quantitative research
- Qual tative research
- ☐ Randomised controlled trial
- ☐ Intervent on study

- ☐ Administrat on of drug / medicine (incl complementary / alternative)
- ☐ Use of a placebo
- ☐ Use of a medical device
- ☐ Human stem cell therapy

- ☐ Other

* Of the tests or procedures to be used, are any on the HREC Register of Approved Tests and Procedures? **NA**

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Consent Process

What method(s) of consent will be used to enable the research to be conducted? NS2.2

Select all that apply. You must **select at least one.**

- Written informed consent
- ☐ Recorded informed consent

- ☐ Parent / Guardian / Carer consent
- ☐ Child's assent with parent / guardian consent
- ☐ Young person 16-17 years consent
- ☐ Child

- ☐ Organisat onal consent, *ie from a CEO, Director, Manager, Principal, etc.*

- ☐ Implied consent
- ☐ Retrospective consent
- ☐ Waiver of informed consent sought
- ☐ Waiver of parent / guardian consent sought

- ☐ Existing consent

- ☐ Other

Research Sites

* List the research sites, ie the communities / schools / hosp tals / organisations etc from which participants will be sourced.

Potential participants will be recruited from within the Newcastle/Lake Macquarie area of NSW (urban), and from surrounding rural areas that are PhARIA 2-3 (rural/remote; w thin a radius of 100km). The reg on has approximately 140 community pharmacies and 120 physiotherapy practices that should provide an adequate area for sampling.

If necessary, the study radius will be increased, if further recru tment is required and/or to reach data saturation.

If more than 10, give number and type, eg "12 NSW government primary schools in the Hunter region"

* Is your research a single site or multi-centre project *(click on icon to select)*? Single site

Participant Numbers

* What is the total number of participants to be recruited at all sites involved in the research? 32

* What is the total number of participants covered by this applicat on? 32

* What is the rat onale for that number?

A maximum of 32 interviews will be conducted.
10-16 pharmacists; 5-8 each from urban and rural/remote areas.
10-16 physiotherapists; 5-8 each from urban and rural/remote areas.

* *Tick to continue*

Eligibility for Expedited Review

Yes ☐ No * Will participants be identifiable, either directly or indirectly, in reporting of the research?

Yes ☐ No * Are the potential part cipants in an unequal relat onship? NS4.3

Yes ☐ No * Does the research involve phys cally invasive procedures? NS2.1

Yes ☐ No * Is there a risk of physical injury to participants? NS2.1

Yes ☐ No * Might the research involve pain or discomfort for participants? NS2.1

Yes ☐ No * Might the research cause participants psychological or emot onal stress? NS2.1

Yes ☐ No * Does the research involve the collection of sens tive personal information?

Yes ☐ No * Could the research expose participants to economic loss or damage to their reputation? NS2.1

Yes ☐ No * Could the research have a negative impact on personal relationships? NS2.1

Yes ☐ No * Will potential participants be offered inducements that could be considered coercive? NS2.2.10; NS3.3.5

Project eligible for expedited review

*

Your project appears to qualify for Negligible Risk Research Expedited Review.
Tick to continue.

Project Details

In the following sect ons, provide a brief 'plain English' descript on of the project. NS1

* Background to project:

Commun ty pharmacists are called upon to prov de sports-related health advice; however, roles for pharmacists in the emerging field of sports pharmacy are limited.[1]

In addition to managing sports-related injuries, evidence ind cates that physiotherapists may be required to provide advice to athletes about the use of medicines and supplements. [2] A recent proposal submitted by the Australian Phys otherapy Associat on, together w th the Australian Physiotherapy Council and Council of Physiotherapy Deans Australia and New Zealand, outlines reasons for granting rights to physiotherapists to prescribe medicines such as anti-inflammatory drugs.

In Australia, with t's expansive geography, consumers living in rural/remote and urban locations may differ in their healthcare needs. Australians living in rural and remote regions have higher rates of injury, and lim ted access to, and use of, primary health care services. [3,4] Accordingly, "the profess onal training, skill and knowledge of the community pharmacist should be more extensively utilised in rural and remote areas, part cularly in areas where commun ty pharmacists can compensate for the lim ted supply of other health profess onals".[5]

There is a pauc ty of l terature describing sports pharmacy, and no Australian studies have compared pharmacists' and physiotherapists' perceptions about this emerging field. Therefore, the proposed study will use qualitative interviews to explore the concept of sports pharmacy among pharmacists and physiotherapists.
Max 250 words

* Aims / hypotheses / questions:

The aim of the study is to explore pharmacists' and physiotherapists' perspectives about sports pharmacy, in rural/remote and urban areas of New South Wales.
Max 150 words

* Research design:

A qualitative approach will be used in this cross-sect onal study. Community pharmacists and musculoskeletal physiotherapists practicing in a primary care setting will be recruited to participate in semi-structured interviews. Interviews will be conducted face-to-face wherever pract cal, although telephone/video sessions may be conducted if necessary. Interviews will be approximately 30 minutes' duration.

The Pharmacy Access/Remoteness Index of Australia (PhARIA) Map Service and Categories is used to identify rural and remote locations; urban is identified as PhARIA 1.[6] The Australian Institute of Health and Welfare considers 'rural and remote' as encompassing all areas outside Australia's major cities (i.e. PhARIA Categories 2-6). These categories are used to allocate government funds under the Rural Pharmacy Maintenance Allowance, to ensure the supply of medicines and pharmacy services.[4,7] Thus, PhARIA Categories 2-6 will be considered for potential inclus on in the 'rural and remote' arm in this study; for practicality, townships closest in proximity to the Newcastle/Lake Macquarie reg on will be considered first.
The two groups of part cipants (pharmacists, physiotherapists) will be recruited in both rural/remote and urban locations, with approximately 5-8 interviews for each group in each locat on.
Data saturation will be considered as the point at wh ch no new themes or information are observed in the data, and will signal an end to further recru tment.[8]
For the purpose of the research, 'primary care' refers to the first point of contact people have with the health system, and relates to the treatment of patients in the commun ty.[9]
Max 250 words

* Potential value and significance of the research:

Pharmacists are one of the most accessible health professionals, part cularly in rural/remote areas of Australia, where community pharmacists often have to compensate for the lim ted supply of other health professionals.[5]

Even though sports pharmacy is an emerging field internationally, pharmacists may feel inadequately prepared for new roles. The paucity of literature on sports pharmacy, as ascertained in a recent systematic review, highlights the need for the proposed research. [1]
Max 250 words

* Experience and skills of researchers. NS1.1

Student Researcher/PhD candidate [redacted] holds a Master of Pharmacy and a Bachelor of Physiotherapy degrees, has 10 years' experience as a pharmacist in Australia, and 2 years experience as a registered physiotherapist. She also has experience teaching into, and coordinating courses in the [redacted] rograms at the University of Newcastle. [redacted] developed a series of lectures in [redacted] for pharmacy students, and is the primary author on [redacted] (principal supervisor) has experience supervising PhD, masters and honours level pharmacy research projects, [redacted] will prov de expertise and input from a pharmacy perspective, and [redacted] from a physiotherapy perspective.
Max 300 words

Participants

* How, and by whom, will potential participants be selected, and
(a) in tially contacted, and
(b) recru ted? NS1.4; NS3.1

Potential participants will be recruited from within the Newcastle/Lake Macquarie area of NSW (urban), and from surrounding rural/remote areas that are PhARIA 2-6. The region has approximately 140 community pharmacies and 120 phys otherapy pract ces that should provide an adequate area for sampling.

Sampling: Purposive and convenience sampling will be used. Initial 'contacts'/potential part cipants will be requested to pass the Study Information on to business or personal contacts ('snowballing' technique).

Initial contact: Potential participants will be contacted by student researcher [redacted] Phys cal business addresses, telephone numbers and email contact details will be accessed from publicly available webs tes identified via Google searches.

Staff in pharmacies and musculoskeletal physiotherapy practices will be contacted "in-person" (i.e. face-to-face or phone) wherever practical to outline/explain the study, disseminate the Participant Information Statement (see attached) and inv te part cipation (see attached 'Conversation Script'). Where in-person contact is impract cal, initial contact will be made via email (see attached 'Inv tation Email'). In the case of email contact, a follow-up phone call will be made to the practice within one week to answer any quest ons and discuss the research (see 'Follow-Up Script').

Recruitment: Individuals who wish to participate may ind cate their intention to do so during the initial contact, or via the telephone number or email address provided on the study informat on. Indiv duals who express interest in participating in the study will be invited to provide an email address to receive an electron c copy of the Participant Informat on Statement and Consent Form (Participant Email and documents attached). A mutually convenient date/time and location for each interview will be arranged via email or phone.
Max 300 words

* Detail the procedure to be used to ensure voluntary and informed consent NS2.2

The study will be outlined during the initial approach (in-person or by email). Potential part cipants will also be provided with the Participant Information Statement wh ch contains a detailed descript on of the research including that part cipat on is voluntary. Signed, informed consent will be obtained prior to interviews.
Max 300 words

* List the inclusion and exclusion criteria NS1.4

Inclusion Criteria: •AHPRA-registered pharmacists/physiotherapists working in a primary care setting (community pharmacy or musculoskeletal physiotherapy practice), w thin the geograph cal areas/suburbs dentified for this study, who work at least one shift per week. Exclusion Criteria: •Registered pharmacists/physiotherapists who do not work in the designated areas, in a primary care setting, or who work less than one shift per week for pharmacists or 1 day per week for physiotherapists.

* What is required of participants?

To participate in a semi-structured interview of approximately 35 minutes' durat on (Interview Guide attached). Interviews will be conducted face-to-face, or via telephone/video-conferencing when face-to-face interviews are impract cal. Face-to-face Interviews will be held at a mutually convenient location, with consideration given to privacy and ambient noise (e.g. in a private room in the pharmacy/phys otherapy pract ce, or a suitable public place that has sufficient privacy).
Max 300 words

* What, if any, benef ts might there be from the research for participants or others? NS1.6

The researchers foresee no immediate benefits for individuals, however the study will contribute to the paucity of information about current and potential roles for pharmacists in sports pharmacy.
Findings from the proposed research may be used to inform the development of sports pharmacy resources.
Max 300 words

* Will participants receive any reimbursements / payments / rewards for participating in the research? NS2.2.10; NS3.3.5 ☐Yes No

Analysis and Reporting

* How will the information you receive be analysed / interpreted? What specific approaches or techn ques (statistical or qual tative) will be employed?

Interviews will be dig tally aud o-recorded to enable transcription. Wr tten transcripts will be coded thematically using standard methods as described by Braun and Clarke.[10]
Descriptive statistics (e.g. means, standard deviat on) will be used to re-present and compare demographic data between participants in the urban and remote study arms.
Field notes will be taken by [redacted] during and immediately following interviews, and these will be cons dered an additional data source i.e. for triangulation.
Max 300 words

* Detail how the results of the research will be reported / disseminated, including appropriate provision of results to participants. NS1.1; NS1.3; NS1.4; NS2.2.6; NS3.1.4; NS3.1.11

Data will be reported in a thesis that will be submitted by [redacted] for the degree of Doctor of Philosophy and in papers for scientific journals or conference proceedings. Individual part cipants or information pertaining to pharmacies/practices will not be identified in any reports arising from the research.

Participants may indicate on the Consent Form if they wish to be prov ded with a summary of the results via email.
Max 300 words

Storage, Access and Disposal of Data

* Detail the mechanisms that will be in place to ensure appropriate storage, access and disposal of data.

To ensure privacy, no names will be used during interviews. Participants and transcripts will be identified by a code number e.g. Pharmacy Part cipant PHRM01, Phys otherapy Part cipant PHYS01. A 'coding key' document will include the part cipant's name, location, and code number; this document will be stored on password-protected computers of the research team
Recorded interviews will be transcribed by the student researcher [redacted] or the transcribing service OutScribe Transcription Service, depending on available research funds. OutScribe Transcription Service currently services most Australian Universities; each transcript onist is required to sign a Conf dential ty Agreement before commencing with OutScribe: [11] "Eth cs Comm ttees often require assurances that qualitative data collected will be handled in an appropriate manner, and rightly so. We are comm tted to the security and confidentiality of your research data and have therefore set in place processes and procedures to ensure our Pol cy is not breached. Each transcriptionist is required to sign a Confidentiality Agreement before commencing with OutScribe and adherence to our processes and procedures are constantly mon tored. All audio and MS Word documents are purged upon payment, unless the client has subscribed to the Repository, in wh ch case the MS Word document is securely stored."
De-identified data will be stored on password-protected University or personal computers and the university server as per ethical requirements. Identifiers (codes and participants' names) will be stored separately from interview data.
Data will be retained securely for a minimum per od of 5 years from completion of the research and managed/stored in accordance with the University's Research Data and Materials Management Guideline (see https://pol cies.newcastle.edu.au/document/view-current.php?id=72) or any successor Guideline, and appl cable Univers ty of Newcastle pol cy provis ons (as amended from time to time). Access to any identifiable data will be limited to members of the research team, unless the part cipant has consented otherwise, except if required by law.
Max 300 words

Safety Implications

Does the proposed research involve work on, use of, or exposure to any of the following?

Yes ☐ No * Cash reimbursements / payments to research participants
Yes ☐ No * Fieldwork / off-campus activity, eg interviews
Yes ☐ No * Recombinant DNA
Yes ☐ No * Genetically modified organisms
Yes ☐ No * Biologically hazardous micro-organisms
Yes ☐ No * Chemically hazardous materials
Yes ☐ No * Human body fluids or tissue
Yes ☐ No * Rad oisotopes / unsealed sources
Yes ☐ No * Ionising radiation
Yes ☐ No * Non-ionising radiat on
Yes ☐ No * Any other potential safety hazard for either participants or researchers?

You may need to submit a Safety Clearance applicat on to the University's Health and Safety Team. Please refer to the Safety in Research and Teaching site for more informat on.

Confirmation

* The information I have provided in this submission is accurate and complete.
(This will close all Help text.)

Comments

Please use this section if you would like to provide add tional information regarding your research that has not been covered elsewhere in the submission, or if you wish to make comments about this submission form.

References

[redacted]

[2] Malek, S., et al. (2014). "A questionnaire examining attitudes of collegiate athletes toward doping and pharmacists as information providers." Can Pharm J 147(6): 352-358.
[3] Noblet TD, Marriott JF, Jones T, et al. Percept ons about the implementat on of phys otherapist prescribing in Australia: a national survey of Australian physiotherapists
[4] Australian Institute of Health and Welfare (2019). Rural & Remote Health. Available from: https://www.aihw.gov.au/reports/rural-health/rural-remote-health/contents/rural-health [Accessed 10 Nov 2019].
[5] The Pharmacy Guild of Australia (2012). Access to Community Pharmacy Services in Rural/ Remote Australia. Available from: https://www.guild.org.au/__data/assets/pdf_file/0017/6164/access-to-community-pharmacy-in-rural-remote-australia-policy7b918033c06d6d6b9691ff000026bd16.pdf [Accessed 10 Nov 2019].
[6] The Univers ty of Adelaide Hugo Centre for Migrat on and Populat on Research (2019). Pharmacy ARIA PhARIA. Available from: https://www.adela de.edu.au/hugo-centre/serv ces/pharia [Accessed 1 Nov 2019].
[7] Pharmacy Programs Administrator (2018). Rural Pharmacy Maintenance Allowance. Available from: https://www.ppaonline.com.au/programs/rural-support-programs/rural-pharmacy-maintenance-allowance [Accessed 5 Nov 2019].
[8] Saunders, B., Sim, J., Kingstone, T. et al. Qual Quant (2018) 52: 1893. https://doi.org/10.1007/s11135-017-0574-8
[9] Australian Government Department of Health (2013). Primary Health Care in Australia. Available from: https://www1.health.gov.au/internet/publications/publishing.nsf/Content/NPHC-Strategic-Framework~phc-australia [Accessed 10 Nov 2019].
[10] Braun, B. & Clarke, V. (2006) Using thematic analysis in psychology, Qual tative Research in Psychology, 3:2, 77-101
[11] Outscribe Australian Transcription Services (2019). Confidentiality and Privacy Policy. Available from: https://www.outscribetranscript on.com.au/Academic/Eth cs-Committees [Accessed 20 Nov 2019].

Declaration

In making this submission, I declare that:

- The research protocol conforms to the *National Statement on Ethical Conduct in Human Research, 2007*, which I have read.
- I undertake to conduct the research in accordance with the approved protocol, the *National Statement*, relevant legislation and the policies and procedures of the University of Newcastle.
- Where I am the project supervisor for the research described herein which will be conducted by a student of the University of Newcastle, I declare that I have prov ded guidance to the student in the design, methodology and considerat on of ethical issues of the proposed research.
- I make this appl cation on the basis that the information it contains is confidential and will be used by the University of Newcastle for the purposes of ethical review and monitoring of the research project described herein, and to satisfy reporting requirements to regulatory bodies. The information will not be used for any other purpose without my prior consent.

Yes No☐ * Each member of the research team is being identified in this submission with his/her knowledge and consent; they have access to the submission; and I have made them aware of the requirement for the research to be conducted according to the approved protocol.

I have uploaded required documents as follows:

Yes * Peer Review Declarat on

Yes * Head of School Declarat on

Yes * Participant Informat on Statement(s)

NA * Verified translations of Part cipant Information Statement(s)

Yes * Participant Consent Form(s)

Yes * All recruitment material, eg advertisements, posters

NA * Surveys / quest onnaires

Yes * Focus group / Interview schedule(s)

NA * Funding applicat on(s) / Contract / Agreement not administred by University of Newcastle

NA * Approval(s) from other HRECs

* I have completed all requirements for this submiss on.

* **Chief Investigator / Project Supervisor:** [redacted]

* Date: [redacted]

Please don't forget to SAVE before ticking 'Complete' or closing the eform

Form published 08 May 2015

Faculty of Health and Medicine Peer Review Sub-Committee

Peer Review of Methodology – Proposal Submitted for Human Ethics Approval

Peer Reviewer Response

CI Name	[removed]
Reviewed by	[removed]
Project Title	[removed]

Please answer the following questions in the space provided (Part G2);

The aims of the research are clearly identified
Yes

The research proposal is well designed and methodologically sound
Yes

The research proposal is supported by an appropriate literature review or justification
Yes

The research procedures are appropriate to the aims of the research
Yes

The proposed study sample is appropriate
Yes, although not all physiotherapists working in primary care treat sports injuries (eg paediatric and neurological physiotherapists) so may not be able to make informed comments

If the research is conducted according to the protocol, it is expected to yield valid and useful data
Yes

The researcher(s) has the necessary expertise to conduct the research and perform the procedures/techniques required by the research
Yes

Where relevant, all methodological issues have been resolved to the satisfaction of the peer reviewer(s)

Further comments if required
Consideration could be given to expanding the aims and interview questions to include discussion as to the desirability of physiotherapists having prescribing rights for medications used in managing sports injuries (eg NSAIDs). As briefly noted in the ethics application, prescribing in physiotherapy is a live topic and may generate a second paper of interest.

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Form HE13: 1210

The University of Newcastle
HUMAN RESEARCH ETHICS COMMITTEE

PEER REVIEW DECLARATION

To be completed and submitted with the following applications:

- **Initial approval – expedited**
- **Initial approval – HREA and HREA Supplement**

Applicant: [redacted]
Title of projects: [redacted]

Peer review confirmation

The research proposal contained herein has been peer reviewed by (*please tick*):

☐ **The following competitive research grant body and given a positive review:**

In: *(year)*

OR

☒ **Reviewed by:** [redacted]

On: *(date)* [redacted]

and it is confirmed that:

- the proposal has been peer reviewed by an experienced researcher in the field of study who is independent of the research and the researchers;
- the aims of the research are clearly identified;
- the research proposal is well designed and methodologically sound;
- the research proposal is supported by an appropriate literature review;
- the research procedures are appropriate to the aims of the research;
- the proposed study sample is appropriate;
- if the research is conducted according to the protocol, it is expected to yield valid and useful data;
- the researcher(s) has the necessary expertise to conduct the research and perform the procedures/techniques required by the research; and
- where relevant, all methodological issues have been resolved to the satisfaction of the peer reviewer.

Title	[redacted]	*First name*	[redacted]	*Last name*	[redacted]
Signed	[redacted]			*Date*	[redacted]
As:	[redacted]				

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

The University of Newcastle
HUMAN RESEARCH ETHICS COMMITTEE

Form HE13: 1211

HEAD OF SCHOOL DECLARATION

To be completed and submitted with the following applications:

- **Initial approval – expedited**
- **Course Related Ethics Approval**

Applicant: [redacted]
Title of projects: [redacted]

NOTE: Where a Peer Review is required, the Head of School Declaration is to be completed after the Peer Review has been completed and the Peer Review Declaration is provided to the Head of School with this Declaration.

Head of School Declaration

Where the Head of School has a conflict of interest with the proposed research, eg an investigator on the project, a member of the research group, or a personal relationship to any member of the research team, this Declaration is to be completed by the Faculty PVC.

I declare that:

- I am satisfied that an adequate peer review has been conducted and that the research proposal is ready for submission for ethics approval;
- the resources required to undertake this project are available; and
- the researchers have the skill and expertise to undertake this project appropriately.

Title	[redacted]	*First name*	[redacted]	*Last name*	[redacted]
Signed	[redacted]			*Date*	[redacted]
As:	[redacted]				

Human Research Ethics Approval: [removed]

Response to Amendments and Conditions

1. Amendment to the Information Statement
    - Requested amendments have been made to the attached Information Statement (highlighted in yellow).

2. Managing research under COVID-19 restrictions
    - All references to face-to-face interviews have been removed from the attached documents.
    - **Difficulty in reaching potential study participants is predicted due to the restrictions on face-to-face contact. Thus, an additional section has been added to the 'Recruitment' document, detailing text to be used in any study advertisement. The researchers propose advertising the study through the University's electronic media channels, Facebook and LinkedIn.**
    - **The researchers acknowledge the increased pressures and demands on the Health System at this time; participants will be offered a $20 Coles/Myer gift voucher as reimbursement for their time, provided upon completion of the interview and administered through the School of [removed] standard financial procedures. A statement about this has been added to the Participant Information Statement (highlighted in yellow).**

Recruitment Conversation Script

Hello XXXXX, my name is [removed], I am a pharmacist and PhD candidate at the University of Newcastle. Along with a team of researchers from the University, I am conducting a study **[removed]**

We are interested in speaking with AHPRA-registered pharmacists or physiotherapists who work at least one shift per week in a primary care setting.

We are conducting this study because Australian research has not previously described pharmacists' and physiotherapists' perspectives about sports pharmacy, even though pharmacists are at times called upon to provide advice to consumers and athletes. The research aims to explore participants' perspectives about sports pharmacy, and data will inform the development of professional guidelines, or a new competency framework for sports pharmacy.

If you are interested in taking part in the study, your input will involve participating in an interview of approximately 35 minutes' duration.

In-person: Here are some copies of the Participant Information Statement which contains further information about the study for yourself and your colleagues. My contact details are included on the last page should you be interested in participating in the research. If you would like to provide an email address, I can forward you an electronic copy of the Participant Information Statement that you can read, or pass on to fellow pharmacists/physiotherapists whom you think could be interested in the research.

Telephone: If you think you might be interested in participating in the research, and would like to provide an email address, I can forward you the Participant Information Statement, which contains further information about the study. We invite you to pass on the study information to any fellow pharmacists/physiotherapists whom you think could be interested in the research.

Do you have any questions about the study?

Thank you for your time.

Recruitment Email Transcript

Dear XXXXX,

[removed]

We would like to request your input into a study being conducted by pharmacist/ PhD candidate [removed] and a team of researchers, at the University of Newcastle, New South Wales. We would like to speak with AHPRA-registered pharmacists or physiotherapists who work at least one shift per week in a primary care setting.

The research aims to explore pharmacists' and physiotherapists' perspectives about sports pharmacy.

Your input will involve participating in an interview of approximately 35 minutes' duration. Please read the attached Information Statement for further information or you can contact the team via reply email [removed]. You will receive a follow-up telephone call in one week to respond to any questions.

Thank you for your interest in the research.

Kind regards,

[removed]
The University of Newcastle
University Drive, Callaghan NSW 2308
M: [removed]
T: [removed]
E: [removed]

Text to be used in Advertisement via Facebook, LinkedIn and/or the University's Electronic Media Channels

Are you an AHPRA-registered pharmacist or physiotherapist and interested in contributing to research in the field of sports medicine?

Researchers are seeking volunteers to help them explore pharmacists' and physiotherapists' perspectives about sports pharmacy through interviews.

Please click the link to the Information Statement for further information, or you can contact the team via reply email [removed]or telephone [removed].

Follow-Up Recruitment Phone Call Transcript

Hello XXXXX, my name is [removed], I am a pharmacist and PhD candidate at the University of Newcastle. Along with a team of researchers from the University, I am conducting a study [removed]**.**

Last week I forwarded an email to your [pharmacy/physiotherapy] practice inviting you to participate in a study about the concept of sports pharmacy.

I'm calling to confirm that you received the Invitation, and whether you have any questions relating to the research that I may be able to answer.

a) *If the pharmacist/physiotherapist indicates he/she is interested in participating in the research, a suitable time/location for the interview may be agreed upon during this telephone call. For face-to-face interviews, consent forms will be provided for signing before the start of interviews; for telephone/video interviews, signed consent forms will be collected via email.*

b) *If the pharmacist/physiotherapist does not indicate an intention to participate in the research:*

If you would like any further information about the study, please don't hesitate to contact me via the contact details provided in the initial email.

Thank you again for your time.

Information Statement

[deleted]
[deleted]
The University of Newcastle
University Drive, Callaghan NSW 2308
[deleted]
[deleted]

Information Statement for the Research Project:
[title deleted]
Document Version 2; dated [deleted]

You are invited to participate in the research project identified above which is being conducted by [deleted] (PhD Candidate) from the School of [deleted]at the University of Newcastle.

The research is part of [deleted] studies at the University of Newcastle, supervised by [deleted] (Chief Investigator) from the School of [deleted].

The Research Team

[deleted]

Why is the research being done?

Sports pharmacy is an emerging field that includes management and prevention of injury, and advice about medicines. Although sports-related injuries in primary care are often managed by physiotherapists, consumers can seek advice and purchase products and Over-The-Counter medicines from community pharmacists. This study aims to explore perceptions of pharmacists and physiotherapists in rural/remote and urban areas about current and potential roles in sports pharmacy, to provide insight into barriers to, and facilitators of, pharmacist input.

What would you be asked to do?

You have been chosen to receive the study information because you are a pharmacist or physiotherapist practicing in a primary care setting, at a location within the designated study area; practices were identified via a Google search. Alternatively, you may have followed the link on an electronic Study Advertisement. You would be asked to take part in an interview of approximately 35 minutes' duration, or to pass the study information on to fellow primary care pharmacists or physiotherapists who may be interested in participating in the research. Video or telephone interviews will be conducted, recorded and analysed by [deleted].

What choice do you have?

Participation in this research is entirely voluntary. Only those people who give their informed consent will be included in the project. You may withdraw from the project at any time (prior to the commencement of analysis) without giving a reason. If you would like to review the transcript please contact [deleted] within two weeks of the interview.

How much time will it take?

The interview should take approximately 30 minutes.

What are the risks and benefits of participating?

Your participation may help to identify and define a new potential area of advanced or specialised pharmacy practice. Although we don't anticipate any risks, there is a slight chance the interview questions may provoke emotions around workplace practices. If this occurs, the interview can be terminated at your request, and you are encouraged to contact your workplace counsellor.

Participants will be offered a $20 Coles/Myer gift voucher as reimbursement for their time, provided upon completion of the interview.

How will the information collected be used and stored?

Non-identifiable data will be presented in a thesis and may be reported in papers for scientific journals or conference proceedings. Individual participants or data pertaining to specific practices will not be identified in any reports arising from the project. A summary of the results will be emailed to each participant. Data will be retained securely for a minimum period of 5 years from completion of the research and managed/stored in accordance with the University's *Research Data and Materials Management Guideline* (see https://policies.newcastle.edu.au/document/view-current.php?id=72) or any successor *Guideline*, and applicable University of Newcastle policy provisions (as amended from time to time). Access to any identifiable data will be limited to members of the research team, unless you have consented otherwise, except if required by law.

What do you need to do to participate?

Please read this Information Statement and be sure you understand its contents before you consent to participate.

Thank you for your interest in my study. If you would like to participate or to obtain further information, please contact [deleted].

[deleted]

Complaints about this research

This project has been approved by the University's Human Research Ethics Committee, Approval No. [deleted]

Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to the Human Research Ethics Officer, Research & Innovation Services, The University of Newcastle, University Drive, Callaghan NSW 2308, Australia, telephone (02) 4921 6333, email Human-Ethics@newcastle.edu.au.

Consent Form

[deleted]
[deleted]
The University of Newcastle
University Drive, Callaghan NSW 2308
[deleted]
[deleted]

Consent Form for the Research Project:

[deleted]

[deleted]
[deleted]
[deleted]
[deleted]

Document Version 1; dated [deleted]

I agree to participate in the above research project and give my consent freely.

I understand that the project will be conducted as described in the Information Statement, a copy of which I have retained.

I understand I can withdraw from the project at any time (up to the point of analysis), and do not have to give any reason for withdrawing.

I consent to participating in an interview and having it recorded.

I understand that my personal information will remain confidential to the researchers, except as required by law.

I have had the opportunity to have questions answered to my satisfaction.

Print Name: _____

Telephone Number (for arranging and/or conducting the interview): _____

If you would like to receive a summary of the study results, please provide your **Email Address** below:

_____

Signature: _____ Date: _____

Physio/Pharmacist Interview Guide

Demographic data/Ice-breaker questions **+/- 3 minutes**

- [deleted]
- [deleted]
- [deleted]

Current roles in sports-related health **8-10 mins**

- [deleted]
- [deleted]

Future roles in sports pharmacy **8- 10 mins**

- [deleted]
- [deleted]
- [deleted]

A Model for delivering sports pharmacy **+/- 5 mins**

- [deleted]
- [deleted]

Physiotherapist-prescribed analgesia **+/- 5 mins**

- [deleted]

Concluding the interview **1-2 mins**

Sports pharmacy is a broad term; is there anything also you would like to add to our conversation?

Would you like to ask me any questions before we conclude the interview?

Thank you for your time and considered responses.

PhaRIA: Field notes: