University of South Australia

Human Ethics Application

Protocol Number :	0000027836
Application Title :	Improving dexterity in novice Podiatry students
Date of Submission :	20/02/2012
Primary Investigator :	Mr Ryan Scott Causby
Other Investigator(s) :	Ms M McDonnell
	AsPr Lloyd Reed

Instructions

Instructions

1 The following provides brief information on how to complete an online ethics application. For more detailed information, please refer to the User Guides available at the UniSA website. Please note that there is also a User Guide for the Principal Supervisor to assist supervisors with the review of student applications. The User Guides also detail the process to follow should you be required to respond to reviewer's comments.

2 The System allows researchers to complete and submit human ethics applications electronically. Applicants navigate their way through the application by answering a number of questions. Sections, pages and / or questions appear based on the answers to previous questions therefore it is advisable that you complete questions sequentially in order to avoid skipping questions unintentionally. At times, word limits may prevent you from providing all the information you need to include. If this is the case, please include the necessary information as either a separate document and add it as an attachment (function available on the Attachments tab on the left hand menu available from the Application Overview screen), or as a page comment. Please refer to the User Guides if you are unsure how to use these functions.

3 Please ensure you enter requested information in the tabs available from the Application Overview screen's left hand menu (Investigators, Attachments etc). Submitted applications that do not contain the required information will be returned to you and therefore the review process will be delayed. Refer to the User Guides if you are unsure how to use these functions.

4 Student applicants: Please note that you must email your supervisor a copy of all attachments included in your application.

A The research activity must not commence until ethics approval is finalised. *

- (●) I agree

Prior Assessment

Non-UniSA HREC

1.1 Has another Human Research Ethics Committee (other than UniSA) reviewed this research project before and does this clearance/approval accurately describe the project as it is to be conducted? *

- ( ) Yes (●) No

UniSA HREC

2.1 Is this application a resubmission of an application that was considered by UniSA HREC and the decision was 'Not Approved: Resubmit', 'Not Approved' or "Approved subject to" and the status has expired (ie amendments were not made within the 6 month timeframe. Please note if your application is Approved subject to and 6 months **has not** lapsed then you should use the application you submitted to make the required changes. *

- ( ) Yes: Not approved: resubmit
- ( ) Yes: Not Approved
- ( ) Yes: Approved subject to and the status has expired
- (●) No

Project details

Ethics training

3.1 Have you had human ethics training in the last 24 months? (Please do not include training you have attended regarding how to use the online ethics system) *

- (●) Yes ( ) No

3.2 Who provided the human ethics training? *

RESA

3.3 Where was the training held? *

University of South Australia City East Campus

Project type

4.1 Main type of research (e.g. staff, PhD). *

- ( ) Honours
- ( ) Course Approval

- (●) PhD
- ( ) Masters by Course work
- ( ) Masters by Research
- ( ) Professional Doctorate
- ( ) Undergraduate
- ( ) Graduate Diploma / Graduate Certificate
- ( ) Staff
- ( ) Other

4.1.2 **Please note that, if you are a student applicant, your application will be forwarded to your principal supervisor once submitted for their approval. If they are satisfied with your application it will be forwarded to the relevant review group. If your supervisor requires changes to be made then your application will be returned to you to make the required changes.**

4.2 Are there any other types of research involved (not identified in 4.1) . Please select all that apply*

- [x] None
- [ ] Honours
- [ ] Course Approval
- [ ] PhD
- [ ] Masters by Course work
- [ ] Masters by Research
- [ ] Professional Doctorate
- [ ] Undergraduate
- [ ] Graduate Diploma / Graduate Certificate
- [ ] Staff
- [ ] Other

4.3 Please list which school(s) the UniSA researchers are from?*

Health Sciences

Project details

5.1 Title of research project*

Improving dexterity in novice Podiatry students

5.2 Plain English title*

Improving dexterity in novice Podiatry students

5.3 What are the aims of your research*

The aim of this study is to evaluate the effect of two separate interventions on the dextrous performance of novice Podiatry students in order to identify an evidence-based strategy to help target students struggling with manual clinical skills. One of the interventions will target afferent input (sensory system) whilst the other will target efferent output (motor system).

5.4 List your research questions or hypotheses. Your protocol should clearly identify the questions which you want your research to answer. *

Does sensory awareness training improve the dexterity of novice Podiatry students?
Do task-oriented exercises improve the dexterity of novice Podiatry students?
Does sensory awareness training improve self-efficacy of novice Podiatry students?
Do task-oriented exercises improve self-efficacy of novice Podiatry students?

5.5 Explain the need for, and value of, your research. Place the aims in the context of existing research or practice. (You must include a list of not more than 10 key references as an attachment to support your answer to this question. These are to be attached to the Attachment tab available from the Application Overview screen).*

Dexterity is an important aspect of manual clinical skill in the Podiatrist. Currently when novice Podiatry students struggle to obtain adequate manual clinical skill levels the solution is to provide greater clinical exposure or maybe even practice the skills on inanimate objects. A recent study by Bitter, Hillier & Civetta (2011) suggests that specific training can improve dexterity over a short period. However it is not known whether this can be generalised to the Podiatric population or what the effects are over an extended period. This could potentially provide a safe and effective intervention for struggling students to improve their long-term manual clinical skills.

5.6 Please describe your research design and methodology (e.g. where will the data collection occur, what will participants be asked to do during the course of data collection, how long will the interview/focus groups/filling out the questionnaire take, etc)*

Initial manual clinical skills training will be provided to all students in a standardised manner incorporating current evidence of procedural teaching of clinical skills. All students who have consented to participate in the experiment will then be administered the 'Intrinsic Motivation Inventory' (IMI), the Edinburgh Handedness Inventory (EHI) and a specific data collection sheet for demographic, medical history, employment history, hobbies and other manual experience information. All information collected regarding demographics and experience will be clarified in a short interview. Subjects will be tested using two recognised tests of dexterity, the Grooved Pegboard Test (Trites 1977) and a Grip-lift task similar to that outlined by Westling & Johansson (1984). Subjects will then be provided time to practice as per the standard protocol within both the Universities. Subsequent to initial training, students will be randomised into intervention and control groups by an independent staff member not involved in the study using computer generated allocation sequences. Intervention groups and control groups will be separated for the required intervention training to take place. Students in each group will be provided with education regarding the importance of rigorous research and the consequence of cross-contamination. Subjects will be instructed not to discuss the required exercises with classmates. In a further effort to ensure compliance, all students will be offered the opportunity to receive instruction in all of the exercise techniques subsequent to final data collection. Subjects will be requested to keep a log of the time spent undertaking the exercises. At the completion of the 4 week training period, in line with the findings by Karni et al. (1995) whereby skill asymptote was met after three weeks of training on a finger sequence task, students will be re-tested using the psychomotor tests outlined previously and asked to fill-in the IMI. Every effort will be made to ensure data collection will occur at a similar time to pre-intervention collection times to avoid confounding from diurnal variation. Throughout data collection, the primary investigator conducting the assessments will remain blinded to group allocations.

5.7 Proposed commencement date*

01/02/2013

5.8 Proposed completion date*

28/02/2014

Resources

Project funding

6.1 Have you applied for funding for this project from any external source?*

◉ Yes and application for the funds has been successful ○ Yes but the outcome of the application is not yet known ○ No

6.2 Please select the relevant project: **(Important note: Once you have selected the correct funded project, you must select "Add project" to save your response)** If you project is not listed in the options provided, you may need to list all investigators involved on the project first as the funded project may be listed under their name (the Investigators tab is available from the Application Overview screen).

6.3 Does your project appear in the list provided above? *

○ Yes ◉ No

6.3.1 What is the name of the fund source?*

Australian Podiatry and Education Research Fund

6.3.2 What is the title of the funded project?*

Improving dexterity in novice Podiatry Students

6.3.3 How much funding have/will you receive? *

$2300

6.4 Does the funding/support provider(s) have a financial interest in the outcome of the research?*

○ Yes ◉ No

6.5 Will the project be supported in ways other than direct funding (eg in-kind support/equipment by an external party)? *

○ Yes ◉ No

Ownership of Data

8.1 Detail who will own the data and the results of your research (student researchers normally own their own research and data unless there is a written agreement between the student and the University / third party; staff research and data is normally owned by UniSA). Please select all that apply.*

- ☐ UniSA
- ☑ Student researcher
- ☐ Other

8.2 Does the owner of the information or any other party have any right to impose limitations or conditions on the publication of the results of this project?*

○ Yes ◉ No

8.3 Please note that it is the researcher's responsibility to ensure that, where required, an appropriate agreement is in place. If you are unsure whether this is needed, please consult the UniSA website . Do you require an agreement regarding ownership or do you currently have an agreement in place?*

○ An agreement is required ○ A signed agreement is in place ◉ An agreement is not required

Data: storage, access, disposal

9.1 The information which will be stored at the completion of this project is of the following type(s). Please select all that apply.*

- ☐ Individually identifiable
- ☑ Re-identifiable
- ☐ Non-identifiable

9.1.1 Give reasons why it is necessary to store information in identifiable or potentially identifiable form (coded).*

Information will be kept in a re-identifiable form so that in the instance that during data analysis further trends or confounders or clarification is required then subjects may be identified.

9.1.2 If the data can be re-identified using a code, specify the security arrangements and access for the code.*

The code will be secured on a computer of the primary researcher, requiring a username and password for access.

9.2 Where will the data be stored (please be specific with the address e.g. If stored at UniSA please specify which campus and the office/room location)*

Data will be stored in the filing cabinet of the primary researcher (incl when he returns to his staff position at the Uni of SA). Should the primary researcher leave the Uni prior to destruction of the information data will be handed over to the primary supervisor for secure storage. The filing cabinet is currently in C8-10 on the City East campus. The filing cabinet and office remain locked.

9.3 For how long will the information be stored after the completion of the project? Why has this period been chosen? *

Information will be stored for 5 years from the completion of the project in line with specified requirements for general research (not SA government)

9.4 In what formats will the information be stored during the research project? (eg. paper copy, computer file on floppy disk or CD, audio tape, USB memory stick, videotape, film). *

During the research project, de-identified coded data collection sheets will be collected for data analysis. During the data analysis process data will be transferred to a statistical program and stored locally on the computer and a back-up on the servers at the University of South Australia

9.5 How will information, in all forms, be disposed after the retention time has lapsed? (Please refer to the Ownership and Retention of Data Policy. The Head of School (or equivalent) must be aware of this process.*

Paper information will be destroyed via a paper shredder and confidential waste bin available in the school of health sciences. Electronic information will be erased from computers and servers. Any electronic information stored on CDrom will be destroyed by cutting up the disc

9.6 Will any other individual(s), organisation(s) or researcher(s) (other than those listed on the Investigators tab) have authority to use or have access to the information? *

○ Yes ◉ No

9.7 Specify the measures to be taken to ensure the security of information from misuse, loss, or unauthorised access while stored during the research project? (eg. will identifiers be removed and at what stage? Will the information be physically stored in a locked cabinet?)*

Identifiers will be removed during the data collection and stored awaiting data analysis at the completion of the data collection period. Information will be stored in a lockable filing cabinet in the locked PhD student office. This is located in the centenary building on the city east campus in room C8-10.

9.8 If the principal researcher leaves UniSA prior to the finalisation of data collection and/or before the storage retention time has lapsed, the researcher(s) will comply with the Universities Ownership and Retention of Data Policy in relation to the storage of data / information collected for, used in, or generated by this project.*

◉ I agree ○ I do not agree

Insurance

10.1 Please refer to the UniSA website : Do you require insurance cover for this project"*

◉ Yes ○ No

10.1.1 Do you have insurance cover for this project?*

○ Yes ◉ No

10.1.2 **Please note that you must provide UniSA HREC with a copy of the insurance cover confirmation letter/email. Final approval cannot be given until the insurance confirmation has been received.**

Project scope

Scope

11.1 Is the activity archival research? A large proportion of activity involving the analysis of documents, publicly available information, or previously collected data may be outside the scope of the University's human research ethics arrangements.*

○ Yes ◉ No

11.2 Is the work being conducted only for UniSA administrative / service delivery purposes?*

○ Yes ◉ No

Scope

12.1 Should the work be characterised as quality assurance or an audit, rather than human research within the scope of the University's human research ethics arrangements?*

○ Yes ◉ No

12.2 Is the work a practical exercise or test conducted for teaching purposes in a University administered facility? (Please refer to Appendix 2 of Guidelines for Evaluation Activities Involving UniSA Students and Staff) *

○ Yes ◉ No

Scope

13.1 Is the work a routine experiment or procedure conducted for teaching purposes in a University administered facility? *

○ Yes ◉ No

13.2 Is the work / data collection conducted by a student only for teaching / learning purposes? *

○ Yes ◉ No

Research type and participants

Research type

14.1 This project involves: (Please select all that apply.)*

- ☐ Research using qualitative methods
- ☑ Research using quantitative methods, population level data or databanks, e.g survey research, epidemiological research
- ☐ None of the above

14.2 What research methodologies will you use? (Please select all that apply.) *

- ☐ Anonymous questionnaires
- ☐ Internet questionnaires
- ☐ Questionnaires requesting intimate personal, identifying, or sensitive information
- ☑ Other questionnaires
- ☐ Face to face interviews which do not request personal or sensitive information
- ☐ Face to face interviews which request personal or sensitive information

- ☐ Telephone survey which does not request personal or sensitive information
- ☐ Telephone survey which requests personal or sensitive information
- ☐ Focus groups
- ☐ Action Research
- ☐ Evaluation research
- ☐ Observation of participant's usual activities
- ☐ Observation of an activity set up for the purposes of the study
- ☐ Access to medical records (or records which contain intimate personal information, and are individually identifiable and are not publicly available)
- ☑ Experiment or testing of a procedure, drug or equipment
- ☐ Use of biological hazards, GMOs or pathogenic organisms
- ☐ Use of carcinogenic and/or toxic chemicals, including heavy metals
- ☐ Use of Radiation (Ionising and/or Non-ionising, but not Ultrasound)
- ☐ Other

14.3 Will you be audio-taping, video-taping, or taking photographs of participants during the course of the study? Please select all that apply.*

- ☐ Audio-taping
- ☐ Videotaping
- ☐ Photographs
- ☑ No

Participant information

15.1 How many participant groups are involved in this research project? *

3

15.2 Please provide the following details for this group: **(Select 'New group' to enter the required information for each participant group. Important note: Once you have completed the required fields, you must select the green tick to save your response)***

Group name	Control
Expected number of participants	29
Age range	18-30
Other relevant characteristics of this group	No history of medical conditions affecting ability to learn psychomotor skills or use their hands. No professional musicians. No previous Podiatric skill experience or other role which may require high levels of dexterity.
Why are these characteristics relevant to the aims of the project?	If subjects come into the study with high levels of dexterity then it will be difficult to determine the actual effects of intervention.
In lay terms and not more than 200 words, explain what the participation will involve	Participants will be required to only participate in usual manual clinical skills teaching. They must be willing to undertake psychomotor tests prior to learning and at the end of the four week intervention period.

Group name	Sensory training group
Expected number of participants	29
Age range	18-30
Other relevant characteristics of this group	No history of medical conditions affecting ability to learn psychomotor skills or use their hands. No professional musicians. No previous Podiatric skill experience or other role which may require high levels of dexterity.
Why are these characteristics relevant to the aims of the project?	It is important that subjects do not enter the study with unusually high dexterity levels as this may confound the effects of intervention
In lay terms and not more than 200 words, explain what the participation will involve	Participants must be willing to undertake psychomotor testing at the prior to skills learning and at completion of the intervention period. During the intervention period participants will be required to undertake regular sensory awareness exercises as outlined.

Group name	Motor training group
Expected number of participants	29
Age range	18-30
Other relevant characteristics of this group	No history of medical conditions affecting ability to learn psychomotor skills or use their hands. No professional musicians. No previous Podiatric skill experience or other role which may require high levels of dexterity.
Why are these characteristics relevant to the aims of the project?	It is important that subjects do not enter the study with unusually high dexterity levels as this may confound the effects of intervention. If subjects have any of the other factors outlined above then their performance of psychomotor tests may be affected.
In lay terms and not more than 200 words, explain what the participation will involve	Participants must be willing to undertake psychomotor testing at the prior to skills learning and at completion of the intervention period. During the intervention period participants will be required to undertake regulartask oriented exercises.

15.3 What is the expected total number of participants in this project at all sites?*

87

15.3.1 Please justify the chosen sample size*

Based on the effect size of 0.75 from the study by Bitter, Hillier & Civetta (2011), with sensory awareness training on the dominant hand only (as this is the hand which will be trained) and a two-tailed t-test comparison, approximately 29 subjects will be required per group with 80% power

Selection of participants

16.1 What process(es) will be used to identify potential participants?*

Participants will be Students in the second year of the Podiatry program at the University of South Australia OR Queensland University of Technology

16.2 Will potential participants be 'screened' or given a test/questionnaire to assess their suitability as a participant for the study?*

◉ Yes ○ No

16.2.1 How will this be done?*

Subsequent to recruitment subjects will be required to have a quick interview with the primary researcher to elicit any details such as medical history, work history or Podiatric experience which may confound the study.

16.3 Describe how initial contact will be made with potential participants.*

Subjects will be approached either face-to-face or via e-mail and invited to participate

16.4 Is an advertisement, e-mail, website, letter or telephone call proposed as the form of initial contact with potential participants?*

◉ Yes ○ No

16.4.1 Please detail how this will be used and/or whether any approval is needed to use this contact method. **Please attach any relevant documents to the Attachments page available from the Application Overview menu.***

The e-mail will invite students to participate and direct them to the 'participant information sheet' for information.

16.5 List the selection and, if appropriate to your study, the exclusion criteria for participants.*

Anyone who has used a scalpel previously, currently works as a professional musician or in another role requiring extraordinarily high levels of dexterity, is on medication or has any neurological condition or musculoskeletal condition which could affect hand function will be excluded.

16.6 If it became known that a person or participant group was recruited to, participated in, or was excluded from the research, would that knowledge expose the person to any disadvantage or risk?*

○ Yes ◉ No ○ Not Applicable

Project start, end, location details

17.1 Will the research be undertaken in Australia?*

◉ Yes ○ No

17.1.1 In which town(s)/city(ies)/State(s) of Australia will the research be undertaken in? *

Adelaide, South Australia
Brisbane, Queensland

17.1.2 In how many Australian organisations will the research be conducted? (Please list all organisations where participants will be specifically recruited from e.g. if recruiting UniSA staff or students, you have at least 1 organisation)*

2

Please note: you must obtain written approval from the organisations where the research will be undertaken and either attach the letter to the application or forward this to the Ethics and Compliance Officer before final approval can be granted for the project. Please refer to UniSA/organisation approval for additional information on the type of approval needed.

17.1.2.1 Please enter the following details for the Australian site(s): (Select 'Add site' to enter the required information.) **Important note: Once you have completed the required fields, you must select the green tick to save your response***

Site name	University of South Australia
Site location	Adelaide, South Australia
Anticipated start date at site	01/02/2013
Anticipated end date at site	28/02/2014

Site name	Queensland University of Technology
Site location	Brisbane, Queensland
Anticipated start date at site	01/02/2013
Anticipated end date at site	28/02/2014

17.2 Will the research be undertaken overseas?*

○ Yes ◉ No

17.3 Are there any time-critical aspects of the research project of which the review committee should be aware?*

◉ Yes ○ No

17.3.1 Describe the time-critical aspects.*

Due to teaching times at the Universities data collection must occur in February and then March/April

Irregular consent process

Limited disclosure / waive consent

18.1 Does the research involve limited disclosure to participants. Refer to Chapter 2.3 of the National Statement. *

○ Yes ◉ No

18.2 Are you asking the HREC / review body to waive the requirement of consent? Refer to Chapter 2.3 of the National Statement.*

○ Yes ◉ No

Covert observations

19.1 Does the research involve covert observation? Refer to Chapter 2.3 of the National Statement.*

○ Yes ◉ No

Deception

20.1 Does the research involve deception. Refer to Chapter 2.3 of the National Statement. *

○ Yes ◉ No

Project type

Project type

21.1 Does the research involve any of the following? Please select all that apply. *

- ☐ Drugs, narcotics, poisons, placebo will be ingested / injected, or an invasive procedure will be administered
- ☐ Clinical trials
- ☐ Cellular therapy
- ☐ The collection and / or use of human samples. This includes tissue, blood or other body fluid collection / extraction
- ☐ Genetic testing and/or genetic research
- ☐ Human gametes or use or creation of human embryos
- ☑ A practice or intervention which is an alternative to a standard practice or intervention
- ☐ Investigating workplace practices which could possibly impact on workplace relationships
- ☐ Conducting the research overseas and recruiting participants
- ☐ None of the above

Non-standard practices or intervention

You have indicated that this research involves a practice or intervention which is an alternative to a standard practice or intervention.

35.1 Explain how the practice or intervention differs from standard practice or intervention. *

Manual clinical skills training of Podiatrists does not traditionally require students to undertake additional exercises (sensory or motor training)

Participants

Recruitment

38.1 Who will you be recruiting as participants for this study? (If there is a high chance that you will be recruiting one of these groups, you should also select that participant group). *

- ☐ General public (over 18 years of age)
- ☐ Members of a collectivity
- ☐ People whose first language is not English
- ☐ People who are illiterate
- ☐ Pregnant women/human foetus
- ☐ Children
- ☐ People who are in a dependent or unequal relationship
- ☐ People who are highly dependent on medical care
- ☐ People with a cognitive impairment
- ☐ Aboriginal and/or Torres Strait Islander peoples
- ☐ People who may be involved in illegal activity
- ☐ UniSA staff
- ☑ UniSA students
- ☐ Not recruiting participants
- ☑ Other

38.1.1 Describe other *

Queensland University of Technology students

38.2 Does the research involve issues likely to be considered significant to Indigenous peoples? *

○ Yes ◉ No ○ Not Applicable

Risk to Participants

Risk to participants

51.1 Please select all that apply. This research project: *

- ☐ Has the potential to expose participants to potential civil, criminal or other proceedings

- ☐ Makes it possible for third parties to identify participants
- ☐ Involves a risk of physical injury
- ☐ Involves human exposure to ionising and/or non-ionising radiation (including X-ray)
- ☐ Involves exposure to disease or infection
- ☐ Involves pain or significant discomfort
- ☐ Involves psychological or emotional stress
- ☐ Involves sensitive personal information
- ☐ Could expose participants to potential loss of professional reputation, market standing, or employability
- ☐ Could result in significant negative impact upon personal relations
- ☐ Offers an inducement which could be considered coercive
- ☐ Involves the participation of people who legally cannot provide voluntary and informed consent for their participation in research
- ☑ None of the above

Right to Privacy

66.1 Does IS42 or the Commonwealth Privacy Act apply to the research (eg access to identified personal data held by third parties subject to privacy regimes)? Refer to the Privacy law*

○ Yes ◉ No

Collection method

Collection method

67.1 Data collected for this research project will be collected directly from participants (e.g. they are completing a question about themselves, their thoughts, their opinions etc)*

◉ Yes ○ No

67.1.1 **Information which will be collected for this research project directly from the participant**

67.1.2 Describe the information that will be collected directly from participants. Be specific where appropriate*

Work history, hobbies, medical and medication history

67.1.3 The information collected by the research team about participants will be in the following form(s). Please select all that apply.*

- ☐ Individually identifiable
- ☑ Re-identifiable
- ☐ Non-identifiable

67.1.3.1 Give reasons why it is necessary to collect information in Individually identifiable or Re-identifiable form.*

This will allow re-identification if during data analysis further confounders are identified or clarification required.

67.2 Data collected for this research project will be collected from another person about the participant (e.g. asking participants' doctors about their patients medical history)*

○ Yes ◉ No

67.3 Data collected for this research project will involve the use or disclosure of information by an agency, authority or organization (other than UniSA)? (e.g. accessing participants' medical records)*

○ Yes ◉ No

67.4 Data collected for this research project will involve using information which you or your organisation collected previously for a purpose other than this research project?*

○ Yes ◉ No

67.5 Describe and justify how you will analyse the data collected from or about the participants*

Information including psychomotor test performance and 'intrinsic motivation inventory' responses will be tested for normality and transformed as required. Data analysis will be undertaken based on an a priori `intention to treat' protocol. To allow for drop-out a mixed model will be used analysing a group by time interaction and comparison of the resulting slopes.

67.6 Indicate whichever of the following applies to this project: Please select all that apply.*

- ☐ Information collected for, used in, or generated by, this project will not be used for any other purpose.
- ☑ Information collected for, used in, or generated by, this project will/may be used for another purpose by the researcher for which ethical approval will be sought.

☐ Information collected for, used in or generated by this project will be used to establish a database/data collection/register for future use by the researcher for which ethical approval will be sought

☐ Information collected for, used in, or generated by, this project will/may be made available to a third party for a subsequent use for which ethical approval will be sought

☐ Other

67.6.1 How might the data be used for the additional purpose? (Please note that the participant information sheet should specify that the data collected may be used for another purpose).*

There is no current intention to use this data for any further project. However, depending on the outcomes of the study it may be useful to allow for the possibility of undertaking longitudinal evaluation.

Participants Relationships

68.1 Is there an existing relationship or one likely to arise during the research, between the potential participants and any member of the research team or an organisation involved in the research?*

◉ Yes ○ No

68.1.1 Specify the nature of any existing relationship or one likely to arise during the research, between the potential participants and any member of the research team or an organisation involved in the research.*

The primary researcher is involved in teaching within the Podiatry program at the University of South Australia

68.1.2 Describe what steps, if any, will be taken to ensure that the relationship does not impair participants' free and voluntary consent and participation in the project.*

No coercion will be involved. Emphasis will be made to the students that participation is completely voluntary and will in no way affect their role as a student or participation in learning.

68.2 Does the researcher / investigator have another role in relation to the participant?*

○ Yes ◉ No

68.3 Will the research impact upon, or change, an existing relationship between participants and researcher / investigator or organisations.?*

○ Yes ◉ No

Consent

69.1 Will consent for participation in this research be sought from all participants? Refer to Chapter 2.2 of the National Statement*

◉ Yes ○ No

69.1.2 Will there be participants who **have** capacity to give consent for themselves?*

◉ Yes ○ No

69.1.2.1 What mechanisms / assessments / tools are to be used, if any, to determine each of these participant's capacity to decide whether or not to participate?*

they must be over 18 years of age and students in a tertiary education setting

69.1.3 Will there be participants who **do not have** capacity to give consent for themselves?*

○ Yes ◉ No

Consent process

70.1 Describe the consent process, ie how participants or those deciding for them will be informed about, and choose whether or not to participate in, the project.*

Participants will be provided with a participant information sheet and encouraged to ask any questions as required. They will be told that they may withdraw consent at any stage in line with usual protocol.

70.2 If a participant or person on behalf of a participant chooses not to participate, are there specific consequences of which they should be made aware, prior to making this decision?*

○ Yes ◉ No

70.3 If a participant or person on behalf of a participant chooses to withdraw from the research, are there specific consequences of which they should be made aware, prior to giving consent?*

○ Yes ◉ No

70.4 Can individual participants be identifiable by other members of their group? (e.g. co-workers, focus group members etc.)*
◉ Yes ○ No

70.4.1 Could this identification expose them to risks? *
○ Yes ◉ No

70.4.2 Will participants receive any incentive/payment (e.g. movie tickets, food voucher) or reimbursement (eg travel expenses) to participant in the study.*
○ Yes ◉ No

70.7 Will consent be specific or extended or unspecified? Refer to statements 2.2.14-2.2.18 of the National Statement*
◉ Specific ○ Extended ○ Unspecific

Risks and benefits

Risks and benefits

Please note that when answering the following questions, only risks beyond those encountered in everyday life are relevant. Refer to Chapter 2.1 of the National Statement

71.1 Are there any risks to participants as a result of participation in this research project (eg physical, psychological, spiritual, emotional, legal, social, financial well-being, employability or professional relationships)?*
○ Yes ◉ No

71.2 What expected benefits (if any) will this research have for the wider community?*

This will provide evidence of the best methods to improve dexterity related to the learning of manual clinical skills in Podiatry. This will therefore create a safer clinic environment and improve skills without putting the public at risk.

71.3 What expected benefits (if any) will this research have for participants?*

Participants will be provided with the insight of how to improve their own dexterity and (hopefully) become a better Podiatrist

71.4 Are there any other risks involved in this research? eg. to the research team, the organisation, others (eg physical, psychological, spiritual, emotional, legal, social, financial well-being, employability or professional relationships)*
○ Yes ◉ No

Risks and benefits cont.

72.1 Is it anticipated that the research will lead to commercial benefit for the investigator(s) and or the research sponsor(s)?*
○ Yes ◉ No

72.2 Is there a risk that the dissemination of results could cause harm of any kind to individual participants - whether their physical, psychological, spiritual, emotional, legal, social or financial well-being, or to their employability or professional relationships - or to their communities?*
○ Yes ◉ No

72.3 Describe how the members of the research team will monitor the conduct of the research? (e.g. Will regular meetings be held between researchers? Will student researchers be in regular contact with their supervisors? etc)*

REgular meetings are held between the primary researcher and the supervisory team.

72.4 **It is mandatory for researchers to report suspected cases of child abuse/neglect, domestic violence, bullying, illegal activities, use of illicit substances, abuse of elderly persons, professional negligence etc.**

72.4.1 Is it likely that this will be disclosed during the course of the project?*
○ Yes ◉ No

Researcher training

73.1 List the relevant qualifications, experiences and /or skills of the research team which equip them to conduct this research*

Prim. res. - PhD candidate, completed Masters, supervised & assessed multiple honours proj. Princ.supervisor

- A/prof, PhD, supervised multiple PhD & hon proj. works clinically & res in neurosc. Ass. superv 1: PhD, Postdoc NHMRC fellow, exp in dexterity research. Ass superv 2: A/prof, PhD, superv multiple PhD proj. exp. Podiatrist

73.2 Do the researchers involved in this research project require any additional training in order to undertake this research?*
○ Yes ◉ No

Reporting of results

74.1 Is it intended that results of the research that relate to a specific participant be reported to that participant?*
○ Yes ◉ No ○ Not Applicable

74.1.4 Explain/justify why results will not be reported to participants.*

Individual performance feedback is outside the scope of the project. Participants may determine their own performance changes whilst undertaking testing. A pdf of any subsequent manuscript will be made available to participants

74.2 Is the research likely to produce information of personal significance to individual participants?*
○ Yes ◉ No

74.3 Will individual participant's results be recorded with their personal records?*
○ Yes ◉ No ○ Not Applicable

74.4 Is it intended that all or some of the results that relate to a specific participant be reported to anyone other than that participant?*
○ Yes ◉ No

74.5 Will research participants have the opportunity to receive a copy of your final report or summary of the findings if they wish?*
◉ Yes ○ No

74.5.1 How will you provide a copy of the final report or summary of the findings*

A pdf of any resulting manuscript will be made available to participants and provided via e-mail if they identify an interest in receiving this information

Reporting of results cont.

75.1 Is the research likely to reveal a significant risk to the health or well being of persons other than the participant (eg family members, colleagues)?*
○ Yes ◉ No

75.2 Is there a risk that the dissemination of results could cause harm of any kind to individual participants - whether their physical, psychological, spiritual, emotional, social or financial well-being, or to their employability or professional relationships - or to their communities?*
○ Yes ◉ No

75.3 How is it intended to disseminate the results of the research? Please select all that apply.*
- ☑ Thesis/dissertation
- ☑ Journal article/s
- ☐ Research paper
- ☑ Conference presentation
- ☐ Commissioned report
- ☐ Other

75.4 Will the confidentiality of participants and their data be protected in the dissemination of research results?*
◉ Yes ○ No ○ Not Applicable

75.4.1 Explain how confidentiality of participants and their data will be protected in the dissemination of research results*

All data will be grouped for data analysis. Individual data will be de-identified.

Declaration

Declaration

The Primary Contact for this project is responsible for the application that is submitted and must be the one to agree to

the following statement.

"On behalf of the research team for this project, I confirm that all members of the research have read the current NHMRC *National Statement on Ethical Conduct in Human Research*. The research team accepts responsibility for the ethical and appropriate conduct of the procedures detailed in this application, confirm that the research team will conduct this project in accordance with the principles described in the *National Statement*, and confirm that the research team will comply with any other condition laid down by the University of South Australia's Human Research Ethics Committee."*****

☑ I agree