

WHAT DOES/DOES NOT REQUIRE HREC APPROVAL?

Developed by Prof Colleen Cartwright, with input from HREC members.

Background:

As the name implies, the SCU Human Research Ethics Committee was established under the NHMRC National Guidelines to review applications from SCU staff and students relating to research; in most cases, an essential component of research (in particular, research which receives government funding) is to publish the research findings. Such publication includes peer-reviewed journal articles, conference presentations which appear in conference proceedings, Honours, Masters and PhD dissertations/theses and for-public-distribution reports.

The HREC noted that ethics applications were being received for coursework components that were not about research and from which no publications were expected, e.g., standard teaching of practical skills, including students working in pairs to learn how to take a patient history, learning to take vital signs, taking blood glucose levels or doing routine laboratory or clinic work. One HREC application noted that: “(t)he inherent challenges with experiential learning have been exacerbated in recent years by the keenness of students to video record segments of practical sessions and demonstrations for review at a later date”. While in many such cases there are clearly ethical issues involved, e.g., student safety, confidentiality and invasive procedures, the HREC agreed that it is not our role to review and/or approve these applications. They are the responsibility of the School, probably in conjunction with the SCU Workplace Health and Safety Unit. A search online found that some other universities advise staff that such activities do not require HREC approval but that responsibility for student safety in such procedures sits at the School or Faculty level. (**Note:** This may be an issue that needs to be considered by Academic Board; the Chair and Deputy Chair will consider the option of making a presentation to Academic Board, which will include clarification of the role of the HREC).

(Note: the discussion in this paragraph draws on the work of Boyd W. *Adapting Research Ethics Principles and Practices to Enhance Professional Coursework Education in Universities*; *J European Higher Education Area*, 2014, No. 2). The HREC agrees that there are convincing arguments for research ethics principles and processes to be adapted and adopted to inform teaching, learning and curriculum development in university courses, to embed a focus on ethical professional practice. This could include students discussing the legal obligations, duty of care and other ethical issues relevant to their profession, as well as ethical evaluation of their practice, professional use of ethical principles and ethical tensions in decision-making. While that does not equate to such courses requiring HREC approval, for the student experience to be as authentic as possible, many courses require students to undertake industry-specific placements which can provide work-based and experiential learning and may also involve students in research. Boyd notes that “... with the increasing adoption of research-and-inquiry pedagogical practices in university teaching, it seems that the principles and practices of the HREC process should naturally play a role

in both the training of ethically-aware graduates, and influence the planning and implementation of research projects (including those) whose primary purpose is as a teaching method.”

What is research?

Currently the decision on whether or not something is research is usually the responsibility of the Faculty’s Associate Dean (Research) (where this is one) or the Executive Dean of Faculty. We also note that some Schools have very vocal proponents of what they do *not* being research, which underlines the importance of the University being clear on what research is and what it is not, and not leaving it to each individual to decide. However, whether or not something is research should also be the first question asked by the Chair and Ethics Manager when an application for ethics approval is received*. The HREC working party on this issue has developed a flow chart which we believe encapsulates the decision-processes required (see attached).

(*Note: Some ethics applications received by the Ethics Office have not had a clear research question, with some researchers stating that their methodology does not require a research question, just research objectives. The HREC takes the position that the application should at least identify what problem/ issue the researcher wants to shed light on and/or what issue the researcher is seeking to understand or influence.)

Level of Approval Required

Most Higher Degree courses (and some undergraduate courses) have a specific requirement for students to conduct their own, individual research. For example, a task outlined in the Unit Information Guide (UIG) for WEL92006: Social Work Field Placement (for the MSW [Q] course), requires students to “conduct a research project on a topic of significance to your field placement ... (and) write up the research in a report format, following APA 6th edition conventions”. The UIG for this unit gives very detailed and helpful information in relation to ethics approval including that “All methods of primary research (e.g. surveys, focus groups) would require an ethics application. Further, a secondary analysis of confidential agency records (e.g. client records) would also require an ethics application.” (See also the Australian Qualification Framework document).

(Note: It has come to the attention of the HREC that some students undertaking their Field Placement for WEL92006 with a particular organisation have been undertaking research both with vulnerable participants and without HREC approval and that this may have been beyond the level of research agreed to in their fieldwork placement agreement. This issue is being further investigated).

While the majority of undergraduate student placements do not involve research projects (e.g., student teachers undertaking classroom placements) a small research project may be the main component of other, community-based placements. While some students contact organisations within their own communities to establish their placements, others are assisted to engage with community organisations by the Office of Community Engagement, through the Live Ideas project. We are aware that some Course Coordinators/Unit Assessors have discussed with the Manager of

the Office of Community Engagement the option of utilising consent forms developed for the Live Ideas project (Note: New proposals are not currently being accepted). However, an examination of those forms indicate that they would not necessarily meet the requirements for ethics approval by the HREC. (Note: the Manager of the Office of Community Engagement has indicated that she is open to further discussion on this point).

Scaffolded Expedited Approval

The majority of undergraduate coursework-related research projects would only require Expedited Ethics approval. Some would only require “Scaffolded Expedited approval” for the whole course, e.g., where all students:

- are instructed in basic, fundamental ethical issues (Autonomy, Beneficence, Non-Maleficence and Justice) and research ethics, as outlined in the National Statement (e.g., research integrity, procedural fairness, information provision and consent, respect, and management of risk) plus behaviour and Codes of Conduct relating to their particular discipline/ profession;
- learn how to write/develop an Information Sheet and Consent Form relevant to the topic of interest (same topic for all students - this should be a non-intrusive, non-controversial topic);
- undertake some basic low or negligible risk research (e.g., recruiting a friend or family member for an interview); and
- write up their results (while an essay to be assessed as part of their coursework is not, strictly speaking, a publication, it is acceptable that this would be the “hard” outcome of their project).

Scaffolded Applications should:

- indicate what professional development and training students have been provided in relation to research and to ethics.
- acknowledge that students have adequately understood that the level of risk is low or negligible (including that they must not recruit vulnerable participants); and
- provide a copy of the Information Sheet and Consent Form that the students will use (and, ideally, to which they have contributed).

Scaffolded HREA Approval

Other coursework-related projects which are low risk but involve vulnerable groups may still be acceptable for Scaffolded Approval but would require a higher level of approval than standard Expedited approval. This could include participants who are considered vulnerable because of their membership of a specific group, but where the project is low risk and all the students will do exactly the same thing and use the same Information Sheet and Consent Form. For example, this could be an Indigenous Studies course, where students each interview an indigenous student or other indigenous person who is not otherwise vulnerable except as a member of that group, about a non-contentious issue. This could also apply to such things as physiotherapy, OT or Social Work

students interviewing someone with a disability. This would need the development of a form that fits in between the HREA and the Expedited application.

Approval for Individual Projects

Individual Expedited Approval is required for low or negligible risk *and* no vulnerable groups. A full HREA is required for projects that involve moderate or high risk *and/or* vulnerable groups. (See Flow Chart).

What is Research? Some criteria for whether or not coursework-required activities are research could include, but not be limited to:

- There is a deliberate intention to use research methods as a teaching tool.
- The research intends to examine real problems.
- The research intends to engage people external to the class, i.e. there will be a recruitment process, which should include a detailed Information Sheet and a comprehensive Consent Form (Note: A Consent Form is not required for an anonymous survey.).
- The method intends to collect or collates data for analysis.
- There may be an intervention in people's lives.

What is not research? Some coursework activities that are not research have been outlined above, i.e., standard teaching of practical skills e.g., class-based practice of health-related processes, including students working in pairs to learn how to take a patient history, learning to take vital signs, taking blood glucose levels or doing routine laboratory or clinic work.

As also noted above, such activities may well involve ethical issues but that does not, in and of itself, make it an issue requiring approval of the HREC.

A suggestion received from a long-serving member of the HREC was that it might be useful, for the university overall, if a Research Methods Course was developed around the structures of the HREC and the National Statement.