

# Unit licences

Unit Licences are designed to manage data collection undertaken by students to fulfill the requirements of a coursework undergraduate or postgraduate unit, and to enable a unit coordinator to obtain an 'umbrella approval' for short-term research projects which are conducted for teaching and learning purposes only.

A Unit Licence may be granted where information, data or samples are collected as part of the teaching or assessment of a unit. This information may be gathered by students undertaking tasks for assessment or where the aim is to assist in the teaching of aspects of data collection, research design and methodology. Where certain criteria are met, the University does not consider the collection of data as research and as such, it remains outside of the scope of Human Research Ethics.

# The unit licence is not ethics approval. It is a licence issued to a specified Unit Coordinator, who undertakes to ensure that the data collection is conducted in an ethical manner.

# Is a Unit Licence a suitable option for your unit?

If the research activity involves any of the following, a unit licence is not suitable:

- Purposive recruitment of vulnerable populations including
  - $\circ$  Women who are pregnant
  - Children (excluding those under 18 years of age who will be involved in activities considered usual instructional or educational activities)
  - o Dependent people
  - Highly medically dependent people
  - People with an impaired capacity
  - People engaged in illegal activities or
  - Aboriginal and Torres Strait Islander people
- Conducting observation in a public setting
- Using secondary source data not in the public domain (excluding social media and secondary source data from workplaces or organisations)
- Using social media data (comments and posts) being collected from individuals (excluding posts and official communications from businesses, organisations and institutions)
- Using data collected/generated in a workplace or at an organisational level that does not have the permission of the data custodian or contains health information
- Using information or data that may raise privacy concerns. Privacy concerns arise when the proposed
  access to or use of the data or information does not match the expectations of the individuals from
  whom this data or information was obtained or to whom it relates
- Working with participants or collecting data from people living in other countries (excluding ECU students who are located at offshore campuses recruiting and collecting data from people within their own country)
- Undertaking a project with greater than negligible risk (inconvenience) to participants
- Undertaking a research project for the purposes of an Honours or Masters by Research degree or
- The results of the study will be published

The Unit Coordinator may wish to consider selecting an activity within the parameters of a unit licence or must contact the Research Ethics Team on 08 6304 2170 or research.ethics@ecu.edu.au to discuss.



# How to apply for a unit licence.

Unit Licences are granted in various ways, depending on how the research questions are being developed. In short, there are three ways of obtaining a Unit Licence based on the following three scenarios:

- The Unit Coordinator selects one standard topic, research question(s) and method that all students will follow. Blanket approval can be given upfront when the topic, questions and methods are known.
- The Unit Coordinator allows students to select their own topic, research questions and methods. Students will need to provide more information before a Unit Licence will be granted.
- A combination approach is applied where some students follow a selected topic, research questions and methods, other students may select their own. Blanket approval can be given upfront for the students where the topic, questions and methods are known, Students who are selecting their own topic, research questions and method will need to provide more information before a Unit Licence will be granted.

The features of the Unit Licence approval process are outlined below.

# One research topic, question(s) and method

| Unit coordinator application  | •Unit Coordinator completes Part A and Part B application   |
|-------------------------------|---|
| Additional documents required | <ul> <li>Unit Outline from Canvas and course outline</li> <li>Information letter and Consent Form</li> <li>Data Collection Instruments</li> <li>Advertisment / Flyer</li> </ul> |
| Review and approval           | •Review undertaken and approval granted by school based Low<br>Risk Ethics Subcommittee Chair   |



# Student selects their own research topic, question(s) and method

| Unit Coordinator application                         | <ul> <li>Unit Coordinator completes Part A application.</li> </ul>   |
|--|--|
| Additional documents required                        | <ul> <li>Unit Outline from Canvas and course outline</li> </ul>  |
| Conditional review and approval                      | <ul> <li>Delegating ethical responsibility to the Unit Coordinator</li> </ul>  |
| Student application submitted to<br>Unit Coordinator | <ul> <li>Each student submits a student application, information letter, consent form and flyer to their Unit Coordinator.</li> <li>Unit Coordinator reviews and accepts ethical responsibility</li> </ul> |

Combination approach - A group of students will have one standard topic, research question(s) and methods that the Unit Coordinator sets and some students in this unit may select their own topic, research questions and methods



| Unit Coordinator application                         | • Unit Coordinator completes Part A and Part B application.   |
|--|---|
| Additional documents required                        | <ul> <li>Unit Outline from Canvas and course outline</li> <li>Information letter and Consent Form</li> <li>Data Collection Instruments</li> <li>Advertisment / Flyer</li> </ul>   |
| Review and approval                                  | <ul> <li>Approval granted AND Conditional approval (for the student<br/>selected topic area) granted to the Unit Coordinator.</li> </ul>  |
| Student application submitted to Unit<br>Coordinator | <ul> <li>For all student selected activity, Each student submits a student application, information letter, consent form and flyer to their Unit Coordinator.</li> <li>Unit Coordinator reviews and accepts ethical responsibility</li> </ul> |

# Frequently asked questions

#### What is a Unit Licence?

The Unit Licence is designed to manage data collection by undergraduate students and some postgraduate students to fulfil the requirement of a unit.

A Unit Licence may be granted where information, data or samples are collected as part of the teaching or assessment of a unit. This information may be gathered by students undertaking tasks for assessment, or where the aim is to assist in the teaching of aspects of data collection, research design and methodology. In each case, students will be undertaking data collection as part of the requirements of a unit. Where these criteria are met, the University does not consider the collection of data as research and as such, remains outside of the scope of Human Research Ethics.

#### Which activities do not require a Unit Licence?

Unit Licence is not required for the following activities:

- teaching activities within ECU classes;
- laboratory-based teaching;
- professional practice; and
- analysis of secondary publicly available data

#### Is the Unit Licence ethics approval?

<u>The Unit Licence is not ethics approval.</u> It is a licence issued to a specified Unit Coordinator, who undertakes to ensure that the data collection from participants by students enrolled in the unit is conducted in an ethical manner.

# What is covered by the Unit Licence?

- Data collection for the purposes of learning activities in undergraduate and some postgraduate units;
- Data collected from participants that will be recruited by the students enrolled in the unit;
- Data that is collected, analysed, written up and presented by students as part of the unit;



• Data collection for the purposes of assessment within a unit. Examples of data collection include work samples, audio/photographic/video recording and interviews;

• Data collection with the purpose of teaching research design and methodology. Students may be required to undertake a very small project (project less than 6 months and/or report not exceeding 10,000 words) as part of the unit requirements. The projects may be identical for all students or may be projects undertaken on an individual or small group basis. Examples of data collection within a project may include observation, questionnaires, surveys, interviewing, audio/photographic/video recording, or administration of tests or stimuli; and

- The Unit Licence can cover the following project configuration:
  - One standard topic, research question(s) and methods that all students will undertake;
  - o Students select their own topic, research questions and methods; or
  - A combination approach: A group of students will have one standard topic, research question(s) and methods and some students may select their own topic, research questions and methods.

Please contact the <u>Research Ethics team</u> if you have any queries on the scope of Unit Licences.

# What is not covered by the Unit Licence?

In general, data collection that involves any of the following will not be covered by a Unit Licence.

- Purposive recruitment of vulnerable populations including;
  - o Women who are pregnant
  - Children (excluding those under 18 years of age who will be involved in activities considered usual instructional or educational activities)
  - o Dependent people
  - o Highly medically dependent people
  - o People with an impaired capacity
  - o People engaged in illegal activities or
  - o Aboriginal and Torres Strait Islander people.
  - Conducting observation in a public setting
  - Using secondary source data not in the public domain (excluding social media and secondary source data from workplaces or organisations)
  - Using social media data (comments and posts) collected from individuals (excluding posts, and official communications from businesses, organisations and institutions)
  - Working with participants in other countries (excluding ECU students who are located at offshore campuses recruiting and collecting data from people within their own country)
  - Using data collected/generated in a workplace or at an organisational level that does not have the permission of the data custodian or data that contains health information
  - Using information or data that may raise privacy concerns
  - Undertaking a project with greater than negligible risk (inconvenience) to participants
  - Undertaking a research project for the purposes of an Honours or Masters by Research degree or
  - The results of the study will be published.

Please contact the <u>Research Ethics team</u> if you have any queries on the scope of Unit Licences.

#### What is secondary source data?

Secondary source data may be defined as having access to and use of data or information that was originally generated or collected for previous research or for non-research purposes, including routinely collected data or information.

# What is the Unit Coordinator's responsibility?

Data collection from human participants recruited by students raises ethical issues.

Unit Coordinators should read and understand the NHMRC National Statement on Ethical Conduct in Human



<u>Research</u> to ensure that the ethical principles contained in the National Statement on Ethical Conduct in Human Research and University policy and procedures are taken into consideration when planning and conducting data collection. This may affect the type of learning activities and assessment tasks that are part of a unit.

Responsibility of the Unit Coordinator includes:

- Being aware of the principles contained in the National Statement, and University policies and procedures relating to data collection from human participants and the possible ethical issues that may be raised;
- Considering these principles when setting the requirements for the unit;
- Ensuring that the objectives of the unit are clearly outlined and that data collection from human participants are necessary to achieve the aims of the unit;
- Being clear the data collection is not a research project and avoiding the use of this terminology throughout the Unit Outline and assignment guidelines;
- Ensuring that the proposed data collection does not involve more than negligible risk to the participant;
- Providing information to students to ensure that data collection from participants is conducted in an ethical manner; and
- Where students are selecting their own topic, research questions and methods, the Unit Coordinator must be satisfied to assume ethical responsibility for the study.
- Where data is collected from the student's workplace, the Unit Coordinator must be satisfied that the data custodian has provided permission for the data to be collected and used to achieve the aims of the unit. This excludes data related to health information.

# How should the Unit Coordinator assess the level of risk?

Initially a Unit Coordinator must assess that the activity does not involve any of the activities which are outside the scope of a unit licence Is a Unit Licence a suitable option for your unit?

<u>Chapter 2.1 of the National Statement</u> classifies the level of risk in three ways:

- 1. negligible risk where the risks should constitute no more than an inconvenience;
- 2. low risk where the risks should constitute no more than a discomfort; and
- 3. greater than low risk for risks that are more significant than a discomfort

A Unit Licence will only be granted to projects which involve only negligible risk to participants. The following describes examples of each.

# 1. Data collection involving negligible risk (inconvenience)

This type of data collection includes:

- non-invasive procedures;
- no apparent risk to participants above the everyday norm; and
- circumstances where participants (and/or organisations) are not identified.

#### Examples

- use of questionnaires/surveys (that do not involve sensitive questions) sent to average adult participants, and returned anonymously so that participants cannot be identified; or
- recording information from groups of participants (not individual participants who will be identifiable) in an educational setting where participants are not identified.

#### 2. Data collection involving low risk (discomfort)

This type of data collection can include:

• non-invasive procedures;



- minimal or low risk to participants above the everyday norm (not including physical, psychological and social risk); and
- circumstances where participants (and/or organisations) may be identified during data collection but steps will be taken to ensure confidentiality.

# Examples

- use of a questionnaire or interview that does not involve sensitive issues, where participants may be identified during data collection; or
- data collection involving children or young people, with parental consent, that is not part of a normal instructional or educational activity.

# 3. Data collection involving greater than low risk (more significant than discomfort)

This type of data collection includes:

- non-invasive procedures;
- Greater than low risk to participants above the everyday norm; and
- circumstances where participants (and/or organisations) may be identified during data collection but steps will be taken to ensure confidentiality.

# Examples

- use of a questionnaire or interview that involves sensitive issues, where participants may be identified during data collection; or
- data collection involving minority groups children or young people, with parental consent, that is not part of a normal instructional or educational activity.

Examples of procedures and data collection that involve greater than negligible risk are:

# Procedures:

- Any form of physically invasive diagnostic, therapeutic or medical procedure such as administration of substances, exercise regime or physical examination;
- Blood, body fluids or tissue samples will be obtained and/or stored;
- Physical pain (i.e. more than mild discomfort) or psychological stress is likely to result from participation
- Investigation of sensitive personal or cultural issues (e.g. suicide, gender identity, sexuality, fertility, gambling, substance abuse);
- Deception of participants, concealment or covert observation;
- Payments or inducements to encourage involvement in the project (which are so significant they might be considered coercive); or
- Disclosure of the results of the project could place persons and/or groups at risk of criminal or civil liability or be damaging to their financial standing, employability, professional or personal relationships.

# Data Collection:

- Collection, use or disclosure of personal information from a Commonwealth, State or Territory agency or a private sector organisation without consent of the participant;
- Audio-visual recordings of participants which may be of a sensitive or compromising nature;
- Use of a questionnaire, survey or interview (where the identity of the participant may or may not be recorded) that might be expected to cause discomfort, embarrassment, or psychological harm; or
- An individual organisation will be identified, and this is likely to be of concern.

# What information needs to be provided to students by the Unit Coordinator?

Students need to be aware that collection of data from human participants raises ethical issues. Students need to be aware of the principles behind informed consent:



- Competence The participant must be competent to give consent.
- Voluntariness Participants must be free to refuse to participate in the project and must be free to withdraw at any time without giving a reason and with no negative consequences.
- Freedom of choice Participants should not be subject to any coercion, inducement or influence that could impair the voluntary nature of consent.
- Informed Information must be provided to the participants about the aims of the project, the requirements of the project, the use of the information collected, and any measures to protect the confidentiality of the information collected. Consent must be obtained based on the information provided to the participant.

# Who should complete the Unit Licence application?

The Unit Coordinator who is responsible for the unit. In some cases, the Course Coordinator may also complete the application.

# What information should be sent with the Unit Licence application?

The application should include the following:

- Completed Part A and B unit licence application form;
- Unit Outline from Canvas (copy and paste into a Word document) and, if applicable, a course outline as handed out to students;
- Completed ethical risk checklist;
- Information letter;
- Consent form (if applicable); and
- Copy of data collection instruments.

# What are the arrangements where students will be conducting individual projects?

For data collection by individual students or small groups of students, it may not be possible at the time of applying for the licence to outline the proposed participants or the nature of the data to be collected. Where data collection is required to teach research design and methodology, the Unit Coordinator may set the requirements of the unit, but the projects will be developed by the students in the unit. In this case, the Unit Coordinator should guide the students in the design of the projects.

The Unit Coordinator is also responsible for reviewing the following:

- the project plan for individual project
- data collection instruments (e.g., questionnaire or interview questions)
- the Information Letter to Participants
- the Consent Form

along with assuming ethical responsibility for the project.

# Where should the application for a Unit Licence be sent?

The Unit Licence application should be submitted to the <u>Research Ethics Team</u>, who will arrange for the Chair (or his or her nominee) of the school's Human Research Ethics Subcommittee to review the application.

# How long will the Unit Licence be granted for?

Initially Unit Licences will be granted for the period of one semester (or the time taken to complete the unit). If the aims and requirements of the unit remain the same AND the Unit Coordinator has not changed, a unit licence may be renewed in subsequent years (rather than a new application being submitted).

# What is an Information Letter to Participants and Consent Form?

The Information Letter to Participants needs to contain information that a reasonable person would think was significant and/or relevant for making the decision to participate in the collection of data. A Consent Form establishes that the participant provided informed consent to participate.



All participants should be provided with a copy of the Information Letter to Participants. Consent to participate is usually established by a signed Consent Form.

# Identical data collection for all students

The Information Letter to Participants and the Consent Form should be developed by the Unit Coordinator.

# Individual student projects

Each individual student or small group of students should develop these documents using the templates and submit the documents with the plan for their data collection. The Unit Coordinator is responsible for ensuring that these documents contain the necessary information.

# Is there a template available for developing an information letter and consent form?

Templates for developing these documents are available on this <u>webpage</u>. The information in red type on the template needs to be amended or deleted based on the data being collected. NOTE: The templates are only appropriate for the unit licence and should not be used for a research project.

# What if the project only involves an anonymous questionnaire/survey?

Anonymous questionnaires require an Information Letter, but they do not require a signed consent form. The Human Research Ethics Committee recommends the following statement appears on the questionnaire: *This is an anonymous questionnaire. You should read the Information Letter carefully as it explains fully the intention of the collection of this information. Please ensure you do not write your name (or any other comments that could identify you) on the questionnaire. By completing the questionnaire, you are consenting to take part in this data collection.* 

#### What level of risk is acceptable?

Assignments and collection of information, data and/or samples undertaken by students for the purposes of fulfilling the requirements of a unit should not normally be of the type that would require review and approval by the University Human Research Ethics Committee, i.e. they should not involve more than negligible risk to the participants.

#### How can confidentiality be protected?

Wherever possible, data should be collected in a way that cannot identify the individual participant and/or their organisation. If this is not possible, participants need to give an assurance that the information will be kept confidential. Data and information that identifies individual participants should be stored securely, and only accessed by the student(s) and the Unit Coordinator. The identity of the individual participants should be removed from the data as soon as possible.

#### What happens to the data collected by the students at the end of the unit?

It is not expected that the data will be used for any other purpose. The Unit Coordinator should request copies of all data (hard copy and electronic) as part of the final report submitted for assessment. Once these have been received, the information should be stored in accordance with the University's retention policies for student assignments and retained by the unit coordinator for 6 months (post appeal period), then destroyed as per <u>Western Australian University Sector Disposal Authority (WAUSDA)</u>.

For further support, with records retention or disposal, please contact imas@ecu.edu.au

#### What monitoring needs to take place?

It is the responsibility of the Unit Coordinator to monitor the conduct of data collection for assessment or teaching requirements of a unit to ensure that it remains within the scope of the Unit Licence, and complies with University policy, the National Statement and other relevant legislative and/or regulatory requirements. The Unit Coordinator must ensure that all data collection will not involve more than normal, everyday risk to the participants, or that the potential risks are either unlikely to occur or extremely minor, and that the proposed management of identified minimal risks is acceptable.



Any significant ethical issue that arises during data collection must be reported immediately to the Research Ethics Team.

The Research Ethics Team may also conduct random audits of assignments conducted by students.

#### What needs to be done if there are any amendments needed?

An application can be made for a variation to the Unit Licence at any time. Examples of variations include a change to the focus of the unit, or student projects that are significantly different to those outlined on the licence.

If the Unit Coordinator changes, a new Application for a Unit Licence must be submitted.

For further information on Unit Licences please contact the Research Ethics Team on 08 6304 2170 or at <u>research.ethics@ecu.edu.au</u>