Guidelines for Compliance with Regulation

1. **Regulation in Research**

1.1. In many instances, research will be governed by regulation and legislation specific to the type of project the researcher wishes to undertake;

1.2 The University has in place governance structures to ensure research that requires approval is appropriately authorised for conduct. This includes committees for overseeing research involving humans and animals, biosafety and radiation, as well as processes for gaining approval from external agencies when needed, such as research subject to the Defence Trade Controls Act;

1.3 In all cases, researchers are responsible for seeking requisite approval for their research when needed. Under no circumstances may a researcher commence a project requiring clearance from either an ethics or biosafety and radiation committee, or an external organisation, until the requisite approval has been granted;

1.4 In many cases, adherence with regulation will entail mandatory training on specific matters, such as authorisation to conduct experiments with animals.

2. Research Involving Human Participants

2.1 All research involving humans as subjects or participants, including use of their body organs, tissues or fluids, must adhere to the *National Statement on Ethical Conduct in Human Research*. In most cases, compliance will entail researchers having to seek approval for the conduct of their projects through the Human Research Ethics Committee (HREC);

2.2 Working with human participants covers a broad range of activities, including (but not limited to) conducting questionnaires, surveys (including anonymous surveys), observations, social media research and physically invasive procedures, as well as accessing personal and health information;

2.3 Researchers must pay particular heed to considerations necessary in the design and conduct of research involving, or potentially affecting, Aboriginal and Torres Strait Islander individuals and communities to safeguard their health, safety, culture and well-being. Guidance is available in *Ethical Conduct in Research with Aboriginal and Torres Strait Islander People and Communities: Guidelines for Researchers and Stakeholders*;

2.4 Researchers must also be aware of the *Privacy Act 1988* and any other regulations and guidelines relevant to the research project such as international regulations and funding body requirements;

2.5 Any unexpected adverse events or complications that occur during the conduct of the research study or during the follow up period after the research must be immediately reported to the Research Ethics and Integrity unit. Failure to do so may result in the withdrawal of the Ethics approval;

2.6 Researchers whose work is likely to be subject to human ethics regulation may access the UC Website and the *Human Research Ethics Manual* for guidance on the framework in which the HREC operates, principles for responsible practice in research, the process for seeking ethics clearance, and the evaluation process.

3. Research Involving Animals

3.1 All projects undertaken at the University that involve the use of animals either for research, teaching or other experimental study must be approved by the Animal Ethics Committee (AEC);

3.2 An animal is defined as any vertebrate (other than a human being) and includes mammals, birds, reptiles, amphibians and fish. Adult decapod crustaceans and cephalopods also fall under the definition of animal for the intents and purposes of the legislation and code that protects the welfare of animals used for research;

3.3 In accordance with the *ACT Animal Welfare Act 1992*, researchers must be authorised to conduct experiments using animals. This includes teaching and research activities. All staff and research students seeking authorisation must undertake the University's mandatory training course, sit an online test and achieve a grade of at least 9 out of 10 before they can be authorised to conduct experiments using animals;

3.4 Staff and students must exercise care in making discretionary decisions regarding the use of animals in research and teaching. In accordance with the *Australian Code for the Care and Use of Animals for Scientific Purposes*, investigators must apply the 3Rs (Replacement, Reduction and Refinement) at all stages of the project. In its decision-making process, the AEC takes into account the 3Rs principle and may not approve or intervene in projects when necessary;

3.5 Any unexpected adverse events or complications that occur during the conduct of the research project or teaching activity must be immediately reported to the Research Ethics and Integrity unit. Failure to do so may result in the withdrawal of the Ethics approval;

3.6 Researchers may seek further guidance on animal ethics regulation and University processes through the UC website and *Procedures of the Operation of the Animal Ethics Committee*.

4. Research Involving Biosafety and Radiation

Biosafety

4.1 The use of Genetically Modified Organisms (GMOs) is subject to the *Gene Technology Regulations 2001* to ensure precautions are taken with GMO-related activities to safeguard the health and safety of people and the environment;

4.2 Researchers must seek approval for proposed dealings involving GMOs through the Institutional Biosafety and Radiation Committee (IBRC). Dealings may include conducting experiments with GMOs; developing, manufacturing or breeding GMOs; importing, transporting or disposing of GMOs;

4.3 Prior to working in the University's PC2 Laboratory Facilities all researchers need to be familiar with the *"Guidelines for Certification of a Physical Containment Level 2 Laboratory"*. Upon reading these guidelines the Laboratory PC2 test must be completed and a score of 100% must be obtained for successful completion of the test. The PC2 Laboratory test must be successfully completed as part of the laboratory induction process;

4.4 Researchers working with GMOs under Notifiable Low Risk Dealings (NLRD) or Dealings Not Involving an Intentional Release (DNIR) must further take the Gene Technology Practices Training course and test;

4.5 Any incident involving GMOs must be immediately reported to the Research Ethics and Integrity unit. Information required includes details of the GMO, whether the GMO escaped beyond the authorised containment, any steps taken to decontaminate facilities and personnel as well as details of the incident (time and date, facility address, personnel involved, licence numbers).

Radiation

4.6 In order to ensure radiation safety in accordance with the *Radiation Protection Act 2006* and the *Radiation Protection Regulation 2007*, proposals to undertake ionising and non-ionising radiation must also be submitted to the IBRC for registration and approval;

4.7 Appropriate licences and training are required for any staff member that deals with a radiation source. Students may not be required to hold a licence if they are under immediate supervision by a licenced staff member at all times;

4.8 All radiation incidents and adverse events (spill, injury, and contamination) must be immediately reported to the Research Ethics and Integrity unit. Information required includes the nature of the involved material, whether people were exposed, any steps taken to decontaminate facilities and personnel and the location of the equipment;

4.9 Researchers may seek further guidance on regulation and processes for seeking University approval through the UC website.

5. Research Involving Export of Defence and Strategic Goods and Technologies

5.1 The *Defence Trade Control Act 2012* regulates the export from Australia to overseas of certain defence and strategic goods and technology listed in the Defence and Strategic Goods List (DSGL). "Export' includes the intangible (i.e. non-physical) transfer or supply and publication of goods and technologies listed in the DSGL;

5.2 The DSGL covers goods and technology that are specifically designed and adapted for use by armed forces (Part 1) and goods that have a dual use i.e. have been designed for particular commercial needs but could be adapted for the military usage (Part 2). Generally speaking, only Part 2 of the DSGL is likely to be applicable to UC researchers;

5.3 Research Services (RS) will conduct periodic audits of research activity at UC to evaluate general areas that may be subject to exports controls regulation. However, ultimately researchers are best placed to determine if the regulation applies to their specific projects;

5.4 Researchers whose projects may be subject to the regulation are responsible for bringing these to the attention of RS before the commencement of any work so that arrangements can be made for a permit to be sought from the Department of Defence;

5.5 RS maintains a Procedures document and information on the UC website to assist researchers in complying with the regulation.

6. Foreign Influence Transparency Scheme

6.1 The *Foreign Influence Transparency Scheme ACT 2018* establishes registration obligations for individuals and entities that undertake certain activities on behalf of foreign principals;

6.2 Foreign principals include: a foreign government, a foreign political organisation, a foreign government related entity, a foreign government related individual;

6.3 Registrable activities include any of the following where the purpose is to attain political or governmental influence: parliamentary lobbying on behalf of a foreign principle, general political lobbying, communications activity, disbursement activities;

6.4 Researchers whose projects may be subject to the regulation are responsible for bringing these to the attention of RS before the commencement of any work so that arrangements can be made for registration of the activities;

6.5 RS maintains information on the UC website to assist researchers in complying with the scheme.