University of Tasmania Human Research Ethics Committee (HREC)

Tier Review Levels for All Submissions

Tier 4: Full HREC Review		
Research Involving:	**National Statement on Ethical Conduct in Human Research (NS) or Other Reference:**	**Submission Examples:**
More than low risk research	• NS Chapter 2.1: Risk and Benefit • NS Chapter 5.1: Institutional responsibilities *(section 5.1.6)*	Research where there is any possibility of harms greater than discomfort. Harms could include: • Physical harms: including injury, illness, pain • Psychological harms: including feelings of worthlessness, distress, guilt, anger or fear related, for example, disclosure of sensitive or embarrassing information, or learning about a genetic possibility of developing an untreatable disease • Devaluation of personal worth: including being humiliated, manipulated or in other ways treated disrespectfully or unjustly • Social harms: including damage to social networks or relationships with others; discrimination in access to benefits, services, employment or insurance; social stigmatisation; and findings of previously unknown paternity status • Economic harms: including the imposition of direct or indirect costs on participants • Legal harms: including discovery and prosecution of criminal conduct
Clinical Trial	• The National Statement on Ethical Conduct in Human Research defines a clinical trial as: *A form of research designed to find out the effects of an intervention, including a treatment or diagnostic procedure.* • The World Health Organisation (WHO) defines a clinical trial as: *Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc. This definition includes Phase I to Phase IV trials.*	• Project to investigate a medication or device for commercial use • Implementation of an educational intervention assigning human participants
Particular categories of research participants	• NS Chapter 5.1: Institutional responsibilities (*section 5.1.6*) • NS Chapter 4.1: Women who are pregnant and the human fetus • NS Chapter 4.4: People highly dependent on medical care who may be unable to give consent • NS Chapter 4.5: People with a cognitive impairment, an intellectual disability, or a mental illness • NS Chapter 4.6: People who may be involved in illegal activities • NS Chapter 4.7: Aboriginal and Torres Strait Islander Peoples	

Waiver of consent for research using personal information in medical research, or personal health information.	• NS Chapter 2.3: Qualifying or waiving conditions for consent *(section 2.3.9)*	
Research where the S95 or S95A guidelines apply	• NS Chapter 2.3: Qualifying or waiving conditions for consent • Privacy Act 1988 • Guidelines under Section 95 of the Privacy Act 1988 • Guidelines approved under Section 95A of the Privacy Act 1988	• Research using data held by a Commonwealth Agency (e.g. ABS) or a private sector organisation
Opt-out approach for research where the S95 or S95A guidelines apply	• NS Chapter 2.3: Qualifying or waiving conditions for consent *(section 2.3.5)* • Privacy Act 1988 • Guidelines under Section 95 of the Privacy Act 1988 • Guidelines approved under Section 95A of the Privacy Act 1988	• A registry
Active concealment or planned deception or aims to expose illegal activity	• NS Chapter 2.3: Qualifying or waiving conditions for consent *(section 2.3.4)*	
Derivation of embryonic stem cell lines or other products from a human embryo	• NS Chapter 3.2: Human biospecimens in laboratory based research • Research Involving Human Embryos Act 2002 • Ethical guidelines on the use of assisted reproductive technology	
Xenotransplantation	• NS Chapter 3.4: Animal-to-human Xenotransplantation	
Prospective collection of human biospecimens for research (including biospecimen 'banking')	• NS Chapter 3.2: Human biospecimens in laboratory based research	Human biospecimens could include: • Tissue • Saliva • Blood • Urine • Breath • Skin pricks
Genomic research (as a general principle, research including genomics will require review by an HREC; however, if no information that can identify an individual is used and no linkage of data is planned, the research may be determined to carry low risk.)	• NS Chapter 3.3: Genomic research	The National Statement on Ethical Conduct in Human Research defines genomic research as: *Research with the potential for hereditary implications which may range from single gene genetic research to whole genome sequencing and any other 'omic' research (e.g. exomic, proteomic, etc) with potential hereditary implications. Genomic research includes the full scope of 'genetic' research.*
Authorised Prescriber Endorsement Applications	• Therapeutic Goods Administration (TGA) Authorised Prescriber Scheme	The Authorised Prescriber Scheme allows authorised medical practitioners to supply therapeutic goods (such as medicines, medical devices or biologicals) that are not included in the Australian Register of Therapeutic Goods (ARTG) to a class of patients with a particular medical condition.
Authorised Prescriber Reports	• Six monthly reports • Adverse Events	• Reports outlining the number of patients who have been treated • Adverse event or product defect reports
Amendments*		**HREC to review any amendments that have been referred to them by the Chair/Deputy Chair or Executive Committee*
Serious Adverse Events		
Major Protocol Deviations		

Annual Safety Reports		

Tier 3: Out of Session Review - Executive Committee

Research Involving:	National Statement on Ethical Conduct in Human Research (NS) or Other Reference:	Submission Examples:
External Low Risk Applications	• NS Chapter 2.1: Risk and Benefit • NS Chapter 5.1: Institutional responsibilities *(section 5.1.7)*	Low Risk Applications submitted from organisations/institutions external to the University of Tasmania
Low Risk Applications*	• NS Chapter 2.1: Risk and Benefit • NS Chapter 5.1: Institutional responsibilities *(section 5.1.7)*	**Executive Committee to review any Low Risk Applications that have been referred to them by the Chair/Deputy Chair due to complexity or significant ethical issues*
Amendments**		**Executive Committee to review any amendments that have been referred to them by the Chair/Deputy Chair*

Tier 2: Out of Session Review - Chair/Deputy Chair

Research Involving:	National Statement on Ethical Conduct in Human Research (NS) or Other Reference:	Submission Examples:
UTAS Low Risk Applications	• NS Chapter 2.1: Risk and Benefit • NS Chapter 5.1: Institutional responsibilities *(section 5.1.7)*	Low Risk Applications submitted from the University of Tasmania
Use of stored human biospecimens for research	• NS Chapter 3.2: Chapter 3.2: Human biospecimens in laboratory based research *(sections 3.2.2 and 3.2.3)*	• Research involving nothing more serious than discomfort to donors, their relatives or their community; and • Gives rise to information that may be important for the health of the donors, their relatives or their community where the identity of the donors will be known to, or can reasonably be ascertained by, those conducting the research or with access to health or research data or information related to donors • Research involving only the use of stored biospecimens and involves no more than low risk
Prior Approval Applications (complex)	• NS Chapter 5.3: Minimising duplication of ethical review	Applications for research projects that have already been granted approval from a NHMRC registered Australian HREC, as the University of Tasmania (UTAS) is not part of the National Mutual Acceptance (NMA) scheme
Amendments*		**The Chair/Deputy Chair can refer any amendment to the Executive Committee or HREC where a higher level of review is deemed necessary*
Prior Approval Amendments (complex)		Amendments for research projects that have already been granted approval from a NHMRC registered Australian HREC, as the University of Tasmania (UTAS) is not part of the National Mutual Acceptance (NMA) scheme
Extension Reports**		***Chair/Deputy Chair to review any Extension Reports that have been referred to them by the Executive Officer due to continuing recruitment or longevity of approval*
Significant Safety Issue (SSI) Notifications		
International/Australia Safety Reports		

Tier 1: Out of Session Review – Ethics Manager		
Research Involving:	**National Statement on Ethical Conduct in Human Research (NS) or Other Reference:**	**Submission Examples:**
Low Risk Audit Applications	• NS Chapter 2.1: Risk and Benefit • NS Chapter 5.1: Institutional responsibilities *(section 5.1.7)*	
Negligible Risk Research (ethics exemption requests)	• NS Chapter 2.1: Risk and Benefit *(section 2.1.7)* • NS Chapter 5.1: Institutional responsibilities *(section 5.1.22)*	• Research where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience • Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk • Research that involves the use of existing collections of data or records that contain only non-identifiable data about human beings
Prior Approval Applications	• NS Chapter 5.3: Minimising duplication of ethical review	Applications for research projects that have already been granted approval from a NHMRC registered Australian HREC, as the University of Tasmania (UTAS) is not part of the National Mutual Acceptance (NMA) scheme
Amendments*		• *The Chair/Deputy Chair can refer any amendment to the Executive Committee or HREC where a higher level of review is deemed necessary*
Prior Approval Amendments		Amendments for research projects that have already been granted approval from a NHMRC registered Australian HREC, as the University of Tasmania (UTAS) is not part of the National Mutual Acceptance (NMA) scheme

Tier 1: Out of Session Review – Executive Officer		
Research Involving:	**National Statement on Ethical Conduct in Human Research (NS) or Other Reference:**	**Submission Examples:**
Minor Amendments		• Administrative changes (e.g. correction of typographical or grammatical errors, changes to contact details) • Changes with little or no ethical issues • Changes in research personnel • Addition of study sites (ensuring this is flagged with Clinical Trial Governance if UTAS) • Changes to Investigator Brochures (EO checks still need to be in place to capture whether Chair review is required i.e., depending on the new safety information that has been included)
Straightforward Prior Approval Amendments	• NS Chapter 5.3: Minimising duplication of ethical review	Amendments for research projects that have already been granted approval from a NHMRC registered Australian HREC, as the University of Tasmania (UTAS) is not part of the National Mutual Acceptance (NMA) scheme • Updated PICF documents • Additional or updated recruitment material • Minor changes to Protocol which do not raise any major ethical issues (noting these already have approval from the lead HREC)
Notification of UTAS Involvement in External Research	• NS Chapter 5.3: Minimising duplication of ethical review	When a University of Tasmania (UTAS) staff member or student is conducting human research at another institution/organisation, where no aspects of the project are taking place in Tasmania and ethics approval has been granted from another NHMRC registered Australian Human Research Ethics Committee (HREC).

Progress Reports		
Extension Reports		
Final Reports		
Document Acknowledgements		• Insurance certificates • File notes • Protocol clarification memos • Sponsor newsletters • Notification of temporary halt or termination of trial for safety reasons, if not able to provide information immediately via a Significant Safety Issue (SSI) notification • Notification of amendments to come, due to new safety information