Austin Health a member of: Melbourne Academic Centre for Health

REx Submission Pathway Checklist

SECTION A: Does the research project involve ANY of the following? (Tick all that apply)		Yes	No
1	Use of a drug or device that is not registered with the Therapeutic Goods Administration (TGA)	☐	☐
2	Use of a product (drug or device) in a clinical trial, when the product is being used in the trial for an unapproved indication, in an unapproved age group or at an unapproved dose	☐	☐
3	Use of a product (drug or device) in a clinical trial, when such use in the trial is to gain further information about an approved use (e.g. pharmacokinetic or pharmacodynamic research)	☐	☐
4*	**A randomised and/or control group trial assessing an intervention(s) i.e. drug/device, clinical, surgical, diagnostic, public health or mental health.**	☐	☐
5	Any risk (or the potential for risk) of physical or psychological harm to the participant, beyond that imposed in routine clinical care	☐	☐
6	Targeted recruitment of Aboriginal people or Torres Strait Islanders	☐	☐
7	Targeted recruitment of vulnerable groups e.g. children or young people under the age of 18; pregnant women; people with a mental illness or intellectual disability, those who are highly dependent on medical care, are unable to provide informed consent, or may have been involved in criminal activities	☐	☐
8*	**Invasive procedures (such as blood samples or biopsies) outside of standard care**	☐	☐
9*	**Use of blood or tissue samples**	☐	☐
10*	**Establishment of a Register, Databank or Biobank**	☐	☐
11	Genetic testing, gene technology or use of Stem Cells	☐	☐
12	Deception of participants, concealment or covert observation	☐	☐
13	Assisted reproductive technology (ART)	☐	☐
14	Xenotransplantation	☐	☐
15	Toxins, mutagens, teratogens or carcinogens	☐	☐
16	Research which may show unknown disabilities; disease status or risk; or have the potential for the discovery of non-paternity	☐	☐
17	Examining potentially sensitive or contentious issues	☐	☐
18	Collection, use or disclosure of identifiable information	☐	☐
19	Request for a Waiver of Consent: National Statement criteria 2.3.10 MUST be addressed *Note: Retrospective chart review by the clinician is able to be done without consent for the purposes of improvement or evaluation of health services as per Health Privacy Principles 2.2 (f) (i) & (iv) & (v) & (vi) therefore a Waiver is not required in this instance*	☐	☐
20	Request for Opt-Out Approach: National Statement criteria 2.3.6 MUST be addressed	☐	☐
21	Exposure to ionizing radiation additional to standard care *Note: If the study involves ionizing radiation please refer to local policy and procedure guidelines*	☐	☐

If you ticked "Yes" to any item in Section A – please submit a High Risk review application
***If answered "Yes" to 4, 8, 9 or 10 please contact the Office for Research for further advice on 9496 4090**
If you ticked "No" to all items in Section A - proceed to Section B

SECTION B: Does the research project involve ANY of the following? (Tick all that apply)		Yes	No
1	Any risk (or the potential for risk) of physical or psychological discomfort to the participant	☐	☐
2	Any foreseeable risk to the participant is no more than inconvenience	☐	☐
3	Aims to establish new knowledge about a disease by collection of information via surveys or interviews	☐	☐
If you ticked "Yes" to any item in Section B – please submit a Low and Negligible Risk review application **If you ticked "No" to all items in Section B - proceed to Section C**			
SECTION C: Does the research project involve ANY of the following? (Tick all that apply)		Yes	No
1	Aims to establish new knowledge by collection of information that has already been collected and is stored by Austin Health only, such as medical record review or database review	☐	☐
2	Aims to identify and/or quantify problems within, or impediments to, good health care delivery and to identify ways of improving those problems	☐	☐
3	Aims to evaluate current health practices or to monitor the introduction of a new practice	☐	☐
If you ticked "Yes" to any item in Section C – please submit an Audit/Quality Improvement application			

Disclaimer: This checklist constitutes guidance only and is not definitive. Please direct any queries to the Ethics and Research Governance Office.