Submission Pathway Checklist

Disclaimer: This is a guide only and is not definitive. Please direct any queries to the Research Ethics & Governance Unit.

This checklist is to help you determine whether your proposed activity will require Ethical Review and what level of Ethical Review.

Irrespective of whether an activity is called research, quality assurance or evaluation, those conducting the activity must consider whether the people involved (e.g. participants, staff or the community) will be exposed to any risk, burden, inconvenience or possible breach of their privacy.

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 pharmacodynamics research	☐	☐
4	A randomised and/or control group trial assessing an intervention(s) i.e. drug/device, or clinical, surgical, diagnostic, public health or mental health intervention.	☐	☐
5	Any risk (or the potential for risk) of physical or psychological harm to the participant, beyond that imposed by routine clinical care *Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk (2.1.6 National Statement)*	☐	☐
6	Targeted recruitment of Aboriginal or Torres Strait Islander Peoples	☐	☐
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	Targeted recruitment of people in dependent or unequal relationships (for example employees of the health services or participants dependent on clinical care)	☐	☐
9	Use of blood or tissue samples	☐	☐
10	Invasive procedures (such as blood samples or biopsies) outside of standard care	☐	☐
11	Establishment of a Registry, Databank or Biobank *Databank: A systematic collection of data, whether individually identifiable, re-identifiable or non-identifiable* (National Statement)	☐	☐
12	Genetic testing, gene technology or use of stem cells	☐	☐
13	Deception of participants, concealment or covert observation	☐	☐
14	Assisted reproductive technology (ART)	☐	☐
15	Xenotransplantation	☐	☐

16	Toxins, mutagens, teratogens or carcinogens	☐	☐
17	Research which may show unknown disabilities; disease status or risk; or have the potential for the discovery of non-paternity	☐	☐
18	Examining potentially sensitive or contentious issues	☐	☐
19	Collection, use or disclosure of identifiable* information	☐	☐
20	Request for a Waiver of Consent: National Statement criteria 2.3.10 MUST be addressed *Note: Retrospective medical record review by the clinician can be done without consent for the purposes of improvement or evaluation of health services as per Health Privacy Principles 2.2(f), 2.2(i), 2.2(iv), 2.2(v) & 2.2(vi) therefore a Waiver is not required in this instance*	☐	☐
21	Request for Opt-Out Approach: National Statement criteria 2.3.6 MUST be addressed	☐	☐
22	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 HREA (more than low risk application)
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 that is more than inconvenience	☐	☐
3	Aims to establish new knowledge about a disease, clinical condition, service or intervention for example, by collection of information via surveys or interviews	☐	☐
4	Aims to establish new knowledge about a disease by collection of information that has already been collected and is stored by Grampians Health only, such as medical record review or database review	☐	☐
5	Activity conducted by a person who does NOT normally have access to the patient's records for clinical care or a directly-related secondary purpose	☐	☐
6	Seeks to gather information about the patient beyond that collected in routine clinical care	☐	☐
7	A clinically significant departure from routine clinical care that is provided to patients	☐	☐
8	Randomisation or the use of a control group or placebo	☐	☐
9	Comparison of cohorts or vulnerable groups	☐	☐
10	Potential to infringe on the rights, privacy or professional reputation of carers, healthcare providers or institutions	☐	☐
11	Contacting patients that is not part of routine care by any means, including but not limited to, telephone, mail or email, and therefore the patient would be unaware that such contact will be made. Contact is made by individuals who would not normally make such routine contact	☐	☐

If you ticked "Yes" to any item in Section B – please submit a Low and Negligible Risk (LNR) 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 identify and/or quantify problems within, or impediments to, good health care delivery and to identify ways of improving those problems	☐	☐

2	Aims to evaluate current health or organization practices or to monitor the introduction of a new practice	☐	☐
If you ticked "Yes" to any item in Section C – please submit a Quality Assurance (QA) application			

*** Table 1 What is meant by 'identifiability' of health information?**

<table>
<tr><td colspan="2">Data used for projects can be identifiable, re-identifiable (coded), non-identifiable or anonymous.

It is possible that projects may involve more than one of the above. For example, a clinician may access identifiable medical records, collect re-identifiable data by using a study code for each patient and keeping a separate log of the study code against the UR number and then provide only the coded data set to a student on clinical placement, so the student only has re-identifiable data to work with.

Please note:
Linking of data sources requires identification
Human biospecimens are considered identifiable or potentially identifiable
Web-based surveys may collect 'identifiable' data if recording the IP address.</td></tr>
<tr><td>Identifiable data:</td><td>Data that allows an individual to be identified. Identifiers may include the individual's name, date of birth, UR or HRN number. For example, a hospital medical record. In particularly small sets of data, even information such as a postcode may be an identifier.</td></tr>
<tr><td>Coded or re-identifiable information:</td><td>Coding is replacing identifiable data with an arbitrary code number. For example, name and UR number can be replaced with a study code, and the Principal Investigator could keep a separate document (e.g. spreadsheet) that has the identifying information along with the study code. If re-identification is required – for example, to check something at a later date – then it can be done. Date of birth can be replaced with age at a particular cut-off point, such as time of diagnosis or admission. It is important to note that data can still be potentially identifiable if it is possible to infer an individual's identity from the information such as asking a hospital employee about their work if they are the only person working in that role.</td></tr>
<tr><td>Non-identified data (anonymised, anonymous, unlinked, not re-identifiable):</td><td>Data that have been collected without personal identifiers and from which no individual can be identified. It should be noted that the term 'deidentified' is used frequently to refer to sets of data from which only names or partial identifiers have been removed. Such data may remain potentially identifiable and is therefore not non-identified data.</td></tr>
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