Waiver of Consent

Procedure

TARGET AUDIENCE and SETTING

Principal Investigator and all staff conducting research at, or under the auspices of, Monash Health.

PURPOSE

To describe the conditions under which a waiver of consent may be granted by the Monash Health Human Research Ethics Committee (HREC), or where Monash Health Research Governance Office (RGO) may accept the approval of a waiver of consent by another HREC.

DEFINITIONS

Consent	A person's or group's agreement, based on adequate knowledge and understanding of relevant material, to participate in research[1].
Confidentiality	The obligation of people not to use private information – whether private because of its content or the context of its communication – for any purpose other than that for which it was given to them[1].
Health information	The following information is health information: (a) information or an opinion about: (i) the health, including an illness, disability or injury, (at any time) of an individual; or (ii) an individual's expressed wishes about the future provision of health services to the individual; or (iii) a health service provided, or to be provided, to an individual; that is also personal information; (b) other personal information collected to provide, or in providing, a health service to an individual; (c) other personal information collected in connection with the donation, or intended donation, by an individual of his or her body parts, organs or body substances; (d) genetic information about an individual in a form that is, or could be, predictive of the health of the individual or a genetic relative of the individual[2].
Personal information	Information or an opinion about an identified individual, or an individual who is reasonably identifiable: (a) whether the information or opinion is true or not; and (b) whether the information or opinion is recorded in a material form or not[2].
Individually identifiable information	Where the identity of a specific individual can reasonably be ascertained. Examples of identifiers include the individual's name, image, date of birth or address.

Re-identifiable (coded) information	From which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets.
Non-identifiable information	From which identifiers have been permanently removed, and by means of which no specific individual can be identified.

PRECAUTIONS/CONTRAINDICATIONS

All researchers at Monash Health must strive to conduct research in the manner indicated in the Human Research Strategic Policy.

PREAMBLE

Depending upon the circumstances of an individual project it may be justifiable to employ alternatives to consent, such as an opt-out approach or a waiver of the requirement for consent, rather than seeking explicit consent[1].

Only a Human Research Ethics Committee (HREC) may approve a waiver of consent, i.e., a waiver of consent cannot be reviewed out of session or through non--HREC levels of ethical review. Before deciding to approve a waiver of consent, a HREC must be satisfied that the project adheres to the *National Statement on Ethical Conduct in Human Research* and the Australian Privacy Principles (APPs).

Monash Health's position is that an opt-out approach is not considered informed consent, but rather, an opt-out approach is a type of waiver of consent, as there is no guarantee that participants will receive and read the information that allows them to decline to participate. Therefore, an opt-out approach requires the same careful consideration by the reviewing HREC as a waiver of consent. The preference is always that informed consent is obtained.

In the context of this document, *waiver of consent* refers to an opt-out approach or a waiver of the requirement for consent.

Where the project is being conducted at Monash Health, the project must also comply with:

- Monash Health's Privacy Policy
- Monash Health's Patient Privacy Information
- Monash Health's Privacy and Confidentiality in Research Procedure

PROCEDURE

For projects reviewed by Monash Health HREC:

When applying for a waiver of consent, the researcher(s) must:

- Submit a cover letter addressed to the HREC, including:
  - A brief overview of the study;
  - A justification for waiving the requirement for consent, addressing each of the 9 criteria contained in paragraph 2.3.6 or 2.3.10 of the *National Statement*;
  - A justification that the research complies with the *Guidelines under Section 95 of the Privacy Act 1988* (s95 guidelines) or the *Guidelines approved under Section 95A of*

the Privacy Act 1988 (s95A guidelines) (as applicable) to ensure that the proposed handling of personal information does not breach the *Privacy Act 1988*;
    - Signature of the Principal Investigator.
- Submit a Protocol where the section on consent clearly describes the scope of the waiver of consent, and the degree of identifiability of the information, i.e., individually identifiable; re-identifiable; non-identifiable.

For projects where Monash Health is accepting the HREC approval by another organisation:

When a person is attending our health service as a patient receiving care, as the carer of a patient, or as an employee of the health service, Monash Health has a responsibility to hold that person's information in confidence.

Therefore, Monash Health Research Governance Office (RGO) may request from the researcher the documentation that was considered by the reviewing HREC, to determine whether the justification for waiving consent can be applied at Monash Health. Whilst a reviewing HREC may have granted approval for a waiver of consent, Monash Health, as the organisation using and disclosing the information, must make an assessment about sharing the information with a third party without consent.

Quality Assurance:

There are circumstances where a Monash Health employee may be accessing data for a Quality Assurance/Improvement (QA/QI) activity. If the employee usually has access to the personal and health information as part of their role and they are proposing to collect, use and disclose this information as part of a QA/QI activity to evaluate, monitor or improve an aspect of Monash Health's service delivery, and the activity pertains only to Monash Health, this is not a waiver of consent. The employee would follow the Monash Health Quality Assurance Procedure.

Other considerations:

Where a project involves a waiver of consent to access large organisational data sets, e.g., the data of a ward, in addition to HREC approval and Governance approval at Monash Health, the waiver of consent would also require endorsement from the Monash Health Data Governance Steering Committee, prior to approval by the Chief Executive Officer.

REFERENCES

1. National Health and Medical Research Council (NHMRC) (2007, updated 2018) *National Statement on Ethical Conduct in Human Research*.
2. *Privacy Act 1988* (Cth).

Document Governance	
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