Work Practice Guideline: Use of Information Sharing Consent Form

Staff this document applies to:

This guideline is for any clinical research team members involved in complex slot allocation in clinical research projects across Austin Health.

Related Austin Health Policies, procedures or guidelines

Research Policy

Purpose

This guideline outlines the correct use of the **Information Sharing Consent Form** for any **HREC-approved research project** that requires sharing participant information for **slot allocation**. The form ensures compliance with ethical standards, privacy laws, and Austin Health policies.

Scope

- Applies to all Austin Health staff involved in research projects requiring data sharing for slot allocation.
- Covers adult participants providing their own consent.
- Applies to projects reviewed and approved by a Human Research Ethics Committee (HREC).

Use

Use this consent form **only for HREC-approved projects** where:

- Limited slots are available for participant enrolment.
- Participant data needs to be shared with an external sponsor or third party to assess eligibility and reserve a slot.

Purpose for sharing data

To allow the clinician to **share information to enable allocation of a slot and to help assess whether a participant meets cohort criteria or eligibility criteria in their research project.**

- To allow the sponsor to **assess whether a participant meets the cohort criteria in their research project.**
- To **reserve a slot** for the participant if preliminary eligibility is indicated.

- Data sharing is **only the first step**; further tests and discussions will confirm final enrolment.

Consent process

- Provide the **Participant Information Sheet and Consent Form** to the patient **under normal Austin Health consent guidelines**:
- Explain the purpose, what data will be shared, and that participation is voluntary.
- Ensure the participant understands that **sharing data does not guarantee enrolment**.
- Allow time for questions and provide answers clearly.

Obtain **signed consent** before sharing any data.

- Give the participant a **copy of the signed consent form** for their records.
- **Medical Record**: Scanned signed consent form.
- Record consent in the participant's **medical record**.

Who can provide consent

- **Adult participants** who can read and understand the information.
- If the **participant** or **legally acceptable representative** cannot read, an independent witness must be present (as per GCP guidelines).
- Consent must be documented with **dated signatures** of:
    - Participant (or representative and witness if applicable).
    - Principal Investigator or delegate.

Who can conduct consent discussion and signing

- The **Principal Investigator or delegate** of the clinical trial that requests data sharing, may conduct the **information sharing consent form discussion.**
- Consent must be documented with **dated signatures** of:
    - Participant (or representative and witness if applicable).
    - Principal Investigator or delegate.

Withdrawal of consent

- Participants may withdraw at any time without affecting their care.
- Document withdrawal in the medical record and study file.
- No further data will be shared after withdrawal, but previously shared data can/will remain with the sponsor.

Potential information to be shared

- Year of birth
- Gender
- Disease type and details (stage, genetic changes/mutations)
- Prior treatments
- Current medications

No identifying information such as name, full date of birth, or address will be shared.

Storage of data

- As PICF is not study specific, signed consent forms to be uploaded into the electronic medical record in accordance with Austin Health policy.
- Data shared must be **de-identified** and transmitted securely.

Compliance

- All processes must comply with:
    - **National Statement on Ethical Conduct in Human Research (2023)**
    - **Australian and Victorian privacy laws**
    - Austin Health research governance requirements