WHAT TYPE OF CONSENT AND WHEN

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The National Statement on Ethical Conduct in Human Research States:

"Consent to participate in research must be voluntary and based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it" (National Statement Chapter 2.3)

Types of Consent

In order of Preference:

- Written
- Verbal
- Implied
- Opt-Out Consent
- Waiver of Consent

Written/Explicit Consent

- Preferred delivery method – Participant/Patient Information Sheet and Consent form
- Consent should never be based on coercion/obligation (NS 2.2.9)
- Metro South accepts NHMRC Templates or a researcher's own as long as key criteria are covered: - aims, background, what participation involves, the risks and benefits
- Not required: technical jargon, witness section, references to 'by law'
- Required: lay language, tick boxes for additional study elements, reference to the reviewing HREC/Complaints management, version control, dates, logos.

Verbal Consent

- Primarily used for telephone participation
- Requires a consistent approach/script
- Needs to be sensitive to the audience and the situation – e.g. still alive?
- Needs to be unambiguous – i.e. details of participation, risks/benefits mentioned
- Follow-up with hard-copy Participant Information & Consent form – if practical/appropriate.

Implied Consent

- Study participation is indicative of consent
- Works well with surveys/questionnaires - Completion implies consent
- Also works for off-site study-based activities – eg. Test kits
- Must always be accompanied by some process of 'informing' - i.e information sheet, provision of information verbally
- Information Sheet can be included at the beginning of a survey/questionnaire; phone conversation can precede sending study activity to participant

Opt-Out Consent*

- Appropriate for large-scale participation studies – i.e. school based & registries
- Consent could be sought but is not feasible to do so
- Is targeted primarily at low risk studies
- Sufficient time/opportunity should be given for a considered response to participation
- Can be viewed as a deceptive/lazy form of consent

(*NS 2.3.5)

Waiver of Consent*

- Is NOT consent
- Is appropriate for low risk applications
- It is not feasible to obtain consent – potential participants moved on/died etc
- Is provided solely by an HREC – which determines whether consent can be sought/otherwise
- In Queensland a 'waiver of consent' is a fundamental requirement to Pubic Health Act access data – in some (ever changing) cases

(*NS 2.3.9)

And Finally…

- Consent is ‘King’ – it applies to all participants in a study – from patients to staff members - any one who has an impact on outcomes
- for all participants the same considerations of participation apply – irrespective of where they come from and what the do